Proposed Re-evaluation Decision PRVD2017-03

Lambda-cyhalothrin

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

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Executive Summary

Health Canada's Pest Management Regulatory Agency (PMRA)

Health Canada's primary objective in regulating pesticides is to protect Canadians' health and their environment. Pesticides must be registered by Health Canada's Pest Management Regulatory Agency (PMRA) before they can be imported, sold, or used in Canada. Pesticides must go through rigorous science-based assessments before being approved for sale in Canada.

All registered pesticides must be re-evaluated by the PMRA on a cyclical basis to make sure they continue to meet modern health and environment safety standards and continue to have value. This may happen sooner if there have been changes in the required information or to the risk assessment methodology. Re-evaluations may result in:

- changes to how products are used;
- changes to product labels to meet current health and environmental standards; or,
- removing products from the market to prevent future harm to health or the environment.

Re-evaluation of Lambda-cyhalothrin

Lambda-cyhalothrin is a synthetic pyrethroid insecticide used to control a broad range of insect pests on a wide variety of sites such as greenhouse food crops, terrestrial food and feed crops, shelterbelts, turf, livestock, structural sites and ornamentals.

When conducting the re-evaluation of lambda-cyhalothrin, the PMRA reviewed scientific information provided by pesticide manufacturers, provinces and Environment and Climate Change Canada, as well as published scientific information. For the environmental assessment, potential risks to organisms on land and in water were examined. For the human health assessment, the following routes of exposure were examined: food, drinking water, exposure when applying the pesticide, and coming into contact with the pesticide after it has been applied.

Key Findings

The human health risk assessment found that there are potential risks of concern from dietary and certain residential exposures to lambda-cyhalothrin. Therefore, cancellation of all food and feed uses and some uses in residential areas are proposed. Exposure from the remaining uses is unlikely to affect your health when used according to the proposed revised label directions.

The environmental assessment found that there are potential risks to pollinators (including bees), beneficial arthropods, mammals, amphibians, aquatic invertebrates and freshwater and marine fish. However, when lambda-cyhalothrin is used according to the proposed revised label directions, it is not expected to pose risks of concern to the environment.

Next Steps

The proposed re-evaluation decision is now open for public consultation for 90 days from the date of this publication. PMRA is inviting the public to submit comments on the proposed re-evaluation decision for lambda-cyhalothrin, including proposals that may refine the risk assessment and risk management. Once PMRA considers the comments and any information that are received during the public consultation period, it will publish a final decision.

Overview

What is the Proposed Re-evaluation Decision for Lambda-Cyhalothrin?

The evaluation determined that under the current conditions of use, the human health risks for most products containing lambda-cyhalothrin do not meet current safety standards. Therefore, the PMRA is proposing to cancel the following uses:

Products used by commercial applicators and growers for:

- All uses on food and feed commodities
- Indoor residential uses

An evaluation of the scientific information has determined that certain uses of lambda-cyhalothrin products have value and do not pose risks to human health or the environment. These uses include:

Products used by commercial applicators for:

- Use on shelterbelt, poplar and willow plantings, outdoor gardens, trees and ornamentals
- Structural use in non-residential areas, golf course turf, sod farms and industrial turf
- Use on tobacco

Before making a final re-evaluation decision on lambda-cyhalothrin, the PMRA will accept and consider written comments on this proposal received up to 90 days from the date of this publication. Please forward all comments to Publications (see contact information on the cover page of this document). The PMRA will consider any additional data/information submitted during the consultation period in the final decision.

What Does Health Canada Consider When Making a Re-evaluation Decision?

Under the *Pest Control Products Act*, all registered pesticides must be re-evaluated by the PMRA on a cyclical basis to make sure they continue to meet modern health and environmental safety standards and continue to have value. The re-evaluation considers data from pesticide manufacturers, published scientific reports, information from other regulatory agencies and other available, relevant information. To reach its decisions, the PMRA applies internationally accepted hazard and risk assessment methods and modern risk management approaches and policies.

For more information on how the PMRA regulates pesticides, as well as the assessment process, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Lambda-cyhalothrin?

Lambda-cyhalothrin is a synthetic pyrethroid insecticide used to control a broad range of arthropod pests on a wide variety of sites including greenhouse food crops, terrestrial non-food, non-feed and fibre crops, terrestrial feed and food crops, shelterbelts, turf, livestock, indoor and outdoor structural sites and surrounding soil, outdoor ornamentals, outdoor wasp and hornet nests.

Lambda-cyhalothrin products can be applied using conventional aerial and ground equipment. They can be applied to cattle as a pour-on or as ear tags. For structural sites, professional applicators can use hand pressurized or power-operated sprayers and pressurized products.

Health Considerations

Can Approved Uses of Lambda-cyhalothrin Affect Human Health?

Risks of concern were identified from dietary and certain residential exposures to lambda-cyhalothrin. Therefore, cancellation of some uses in residential areas and cancellation of all food uses are proposed. Mitigation measures are proposed for non-food uses in non-residential areas. Exposure from the remaining uses is unlikely to affect your health when used according to the proposed revised label directions.

Potential exposure to lambda-cyhalothrin may occur through the diet (food and drinking water), when handling and applying products containing lambda-cyhalothrin, or during contact with treated surfaces. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed. The health effects noted in animals occur at doses which are much higher than levels to which humans are normally exposed when pesticide products are used according to label directions. In addition, for lambda-cyhalothrin, extensive mitigation measures are proposed to further reduce exposures for certain uses.

In laboratory animals, lambda-cyhalothrin ranged from moderate to high acute oral toxicity. Lambda-cyhalothrin is of low to moderate acute dermal toxicity. Lambda-cyhalothrin produced moderate acute inhalation toxicity and slight dermal irritation. Lambda-cyhalothrin caused mild eye irritation, and did not cause allergic skin reactions.

Registrant-supplied short- and long-term (lifetime) animal toxicity tests, as well as information from the published scientific literature, were assessed for the potential of lambda-cyhalothrin to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity and various other effects. The most sensitive endpoints for risk assessment included effects on the nervous system and reproductive organs. In addition, there was evidence that

young animals were more sensitive than adult animals to cyhalothrin toxicity as demonstrated by reduced offspring body weight at a dose which was not toxic to the mothers, as well as other indicators of sensitivity. Longer-term dosing with cyhalothrin resulted in mammary and uterine tumors in mice. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Residues in Food and Drinking Water

Dietary risks from food and drinking water are of concern. In order to address these concerns, cancellation of all registered food and feed uses is proposed, unless there is information/data submitted during the consultation period that would help address the dietary risk concerns identified.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose (ARfD) or chronic reference dose (acceptable daily intake or ADI). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects. For the cancer assessment, a lifetime cancer risk that is less than one-in-a-million (1×10^{-6}) is generally considered an acceptable risk for the general population when exposure occurs through pesticide residues in/on food and drinking water, and to otherwise unintentionally exposed persons.

Potential exposure was estimated from residues of lambda-cyhalothrin in both treated crops and drinking water. Exposure to different subpopulations, including children and women of reproductive age, were considered. Food residue estimates were based mostly on monitoring data and included percent crop treated information and chemical-specific processing factors when available. Drinking water estimated environmental concentrations (EECs) were based on the modelling of lambda-cyhalothrin residues in surface water using the typical use rate for turf, which represents the highest outdoor broadcast application rate in Canada.

The acute dietary exposure (from food and drinking water) estimates at the 99.9th percentile for the general population and all other subpopulations range from 364% of the ARfD (children 6-12 years old) to 913% of the ARfD (adults 20-49 years old). The chronic dietary exposure estimates for the general population and all other subpopulations range from 40% of the ADI (youth 13-19 years old) to 115% of the ADI (children 1-2 years old). The dietary cancer risk estimate for the general population is 5×10^{-6}. Thus, acute, chronic and cancer dietary risks from exposure to lambda-cyhalothrin are of concern.

The *Food and Drugs Act* prohibits the sale of adulterated food; that is, food containing a pesticide residue that exceeds the specified maximum residue limit (MRL). Pesticide MRLs are specified for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. An MRL represents the maximum amount of residues that may remain on food when a pesticide is used according to label directions, and serves as a food safety standard. The Canadian Food Inspection Agency is responsible for monitoring the Canadian food supply for pesticide residues and the determination of compliance with MRLs specified by Health Canada.

Canadian MRLs for lambda-cyhalothrin are currently specified for a wide range of commodities. Residues in all other agricultural commodities, including those approved for treatment in Canada but without a specific MRL, are regulated under Subsection B.15.002(1) of the *Food and Drugs Regulations*, which requires that residues do not exceed 0.1 ppm. A complete list of MRLs specified in Canada can be found on the PMRA's MRL Database, an online query application that allows users to search for specified MRLs, regulated under the *Pest Control Products Act*, for pesticides or food commodities (http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php). As a result of the re-evaluation, all Canadian MRLs for lambda-cyhalothrin are proposed for revocation and to align with the proposed decision to cancel all registered food and feed uses.

Risks in Residential and Other Non-Occupational Environments

Residential cancer and non-cancer risks from turf postapplication exposures are of concern, therefore mitigation to further limit exposure is proposed.

Residential postapplication exposure may occur while performing activities on or around turf in residential areas treated with lambda-cyhalothrin by commercial applicators. Turf postapplication risks are of concern for children (1<2 years) through hand-to-mouth exposure.

Since risks of concern were identified for children, turf application in residential areas (except golf courses) is proposed for cancellation. Application to non-residential turf is permitted. Proposed label directions will include definitions of residential areas and non-residential areas, with specific examples for each.

Residential cancer and non-cancer risks from outdoor garden and tree postapplication exposures are not of concern.

Residential postapplication exposure may occur while performing activities on or around outdoor gardens and trees in residential areas treated with lambda-cyhalothrin by commercial applicators. Outdoor gardens and tree postapplication risks are not of concern.

Residential cancer and non-cancer risks from indoor structural postapplication exposures are of concern. Therefore, cancellation of all indoor uses in residential areas is proposed.

Residential postapplication dermal and inhalation exposure may occur while performing activities in indoor residential areas treated with lambda-cyhalothrin by commercial applicators. Incidental oral exposure (hand-to-mouth) may also occur for children playing in treated areas.

The following postapplication scenarios were assessed: application for bedbugs, band and spot application, and crack and crevice application. Both cancer and non-cancer risks of concern were identified for all lifestages from dermal exposure for all scenarios except crack and crevice application. Both cancer and non-cancer risks of concern were identified for children from incidental oral exposure for all scenarios including crack and crevice application. Revised label directions are proposed to specify that crack and crevice applications are only permitted in non-residential areas.

All indoor residential applications of lambda-cyhalothrin are proposed for cancellation. Proposed label directions will include definitions of residential and non-residential areas, with specific examples of each. Crack and crevice applications will be defined and specific use directions for these applications will be included.

Aggregate risks are not of concern when the above-noted mitigation is considered.

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

The aggregate assessment was based on exposures for uses that did not have any risk concerns. For lambda-cyhalothrin, these included exposure from drinking water, and residential exposures from treated gardens and trees and from turf in golf courses.

An aggregate assessment for adults, youth (11<16 years), and children (6<11 years) was conducted based on chronic (background) dietary exposure from drinking water and dermal exposure from gardens and trees, and turf. No risks of concern were identified for all scenarios and lifestages.

Human biomonitoring data were also available and used to inform the risk assessment based on the current registered uses of lambda-cyhalothrin, including food uses. The non-cancer and cancer aggregate assessments using this biomonitoring data also identified risks of concern, supporting the conclusions of the overall risk assessment that risk mitigation is required.

Occupational Risks

Occupational risks to handlers are not of concern for all non-food uses when used according to the proposed revised label directions.

Risks to handlers are not of concern for all non-food scenarios, including use on chokecherry shelterbelt, tobacco, poplar and willow plantings or other outdoor ornamentals, indoor environments, turf in golf courses, sod farms, and non-residential turf. Based on the precautions and directions for use on the original product labels reviewed for this re-evaluation, most risk estimates associated with mixing, loading, and applying activities exceeded target dermal and inhalation margins of exposures (MOEs) and are not of concern with additional personal protective equipment (PPE).

Occupational postapplication risks to workers are not of concern for all non-food uses when used according to the proposed revised label directions.

Postapplication occupational risk assessments consider exposures to workers entering treated sites in agriculture and residential/commercial areas and performing various activities. For all outdoor non-food uses, postapplication risks to workers exceeded target dermal MOEs and are not of concern with the proposed restricted-entry intervals.

For indoor structural uses (for example, warehouses, food processing plants) following crack and crevice applications, no risks of concern were identified for postapplication exposure for workers.

Environmental Considerations

What Happens When Lambda-cyhalothrin is Introduced Into the Environment?

Lambda-cyhalothrin is not expected to pose risks of concern to the environment When used according to the proposed revised label directions.

Lambda-cyhalothrin can enter non-target terrestrial and aquatic habitats through spray drift, and aquatic habitats through run-off. In soil and surface waters, it can last for several weeks under certain environmental conditions, breaking down gradually through natural processes. In soil, lambda-cyhalothrin binds strongly to soil particles and is not likely to move downwards through soil towards groundwater. In surface waters, lambda-cyhalothrin tends to move quickly (within hours) to sediments. Lambda-cyhalothrin is rarely detected in groundwater, treated water for drinking, or surface waters such as lakes and rivers. Lambda-cyhalothrin is not likely to enter the atmosphere and be subject to long-range transport.

In laboratory studies, at high concentrations, lambda-cyhalothrin was found to be toxic to pollinators (including bees), beneficial arthropods (parasitic insects and predatory mites), mammals, amphibians, aquatic invertebrates (water fleas and sediment dwelling organisms), and freshwater and marine fish. If lambda-cyhalothrin is used at labelled application rates without any risk reduction measures, it may cause adverse effects on the organisms listed above. Therefore, mitigation measures are proposed in order to reduce potential exposure of non-target organisms and reduce environmental risks. When lambda-cyhalothrin is used in accordance with the proposed revised label directions, it is not expected to pose risks of concern to the environment.

Value Considerations

What is the Value of Lambda-cyhalothrin?

Lambda-cyhalothrin has one of the broadest registered use patterns for the synthetic pyrethroids and is widely used in Canadian agricultural and structural pest management. It is also one of the main alternatives to organophosphates and neonicotinoids, and it is a valuable tool in resistance management. Lambda-cyhalothrin is the only active ingredient registered for suppression of black vine weevils in strawberries, and for control of a number of labeled pests on poplar and willow grown under short rotation intensive culture.

Lambda-cyhalothrin has a role in an Integrated Pest Management approach to manage pests in structural sites. It is used by professional pest control applicators in residential settings to treat bedbugs, cockroaches, and ants.

Lambda-cyhalothrin is important in the control of face flies and horn flies on beef and non-lactating dairy cattle, and the control of lice and ticks on beef cattle and calves as it is an important tool where pesticide resistance is of concern.

Proposed Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of lambda-cyhalothrin, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

To protect the general population from dietary exposure to lambda-cyhalothrin residues on food, the following requirements are proposed:

- The use of lambda-cyhalothrin on all food and feed commodities is to be cancelled.
- For all food uses (including imports), it is proposed that MRLs be revoked. As this may cause trade conflicts between Canada and other countries, the PMRA will consult with all interested stakeholders before making a final decision on MRL changes.

To protect homeowners, the following requirements are proposed:

- All indoor structural uses in residential areas are to be cancelled.
- All indoor structural applications in non-residential areas are to be limited to crack and crevice applications only.
- Turf application in residential areas is to be cancelled.
- Label directions are to be added clarifying that turf applications are permitted only for golf courses, sod farms, and non-residential areas.
- Label directions are to include definitions of residential and non-residential areas, with specific examples for both outdoor uses and indoor structural uses.
- Definition of crack and crevice application, with specific use directions, is to be included on the label.
- Label statement indicating to apply only when the potential for drift to areas of human habitation or areas of human activity (excluding golf courses) such as houses, cottages, schools and recreation areas including parks, school grounds, and playing fields is minimal, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

Environment

To protect non-target organisms and reduce environmental risks, the following requirements are proposed:

- Environmental hazard statements will be required for pollinators, beneficial arthropods, mammals, and aquatic organisms. On crops preferred by pollinator species, label statements will advise to avoid application during periods of bloom, or to apply during the evening when bee foraging is minimal.

- Spray buffer zones between the point of application and non-target aquatic habitats will be required.
- Label statements to reduce the potential for runoff will be required.

The proposed mitigation measures are outlined in Appendix XIV.

What Additional Scientific Information Is Requested?

No additional data are required.

Next Steps

During the consultation period, registrants and stakeholder organizations may submit further data that could be used to refine risk assessments (cancer mode of action data, exposure or use information), which could result in revised risk-reduction measures. Stakeholders who are planning to provide information of this type are advised to contact the PMRA early in the consultation period, for advice on studies or information that could be submitted to help refine the relevant risk assessments. Consideration of any additional data/information submitted during the consultation period to further refine the health risk assessment may or may not result in a change to this proposal.

Before making a final re-evaluation decision on lambda-cyhalothrin, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[1] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

[1] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Lambda-cyhalothrin is under re-evaluation in Canada as described by the Pest Management Regulatory Agency (PMRA) in the 20 December 2011 Re-evaluation Note REV2011-05, *Re-evaluation of Pyrethroids, Pyrethrins and Related Active Ingredients*. Lambda-cyhalothrin is a broad spectrum insecticide belonging to the Insecticide Resistance Management Mode of Action (MoA) group 3A. Lambda-cyhalothrin acts on the nervous system of insects, disrupting the function of neurons by interaction with the sodium channels. It is a non-systemic insecticide that works by contact and stomach action, and has rapid knockdown, long residual activity, and repellant properties.

Following the re-evaluation announcement for lambda-cyhalothrin, the registrant of the technical grade active ingredient, and primary data provider in Canada indicated continued support for all registered label uses.

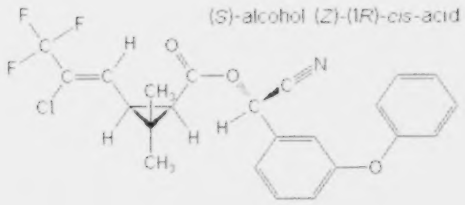
Currently registered products containing lambda-cyhalothrin are listed in Appendix I.

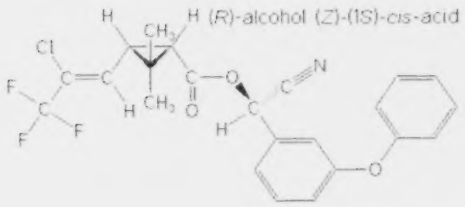
2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient.

Common name		Lambda-Cyhalothrin
Function		Insecticide
Chemical Family		Pyrethroid
Chemical name		
1	**International Union of Pure and Applied Chemistry (IUPAC)**	*rac*-(*R*)-cyano(3-phenoxyphenyl)methyl (1*S*,3*S*)-3-[(1*Z*)-2-chloro-3,3,3-trifluoroprop-1-en-1-yl]-2,2-dimethylcyclopropane-1-carboxylate
2	**Chemical Abstracts Service (CAS)**	(*R*)-cyano(3-phenoxyphenyl)methyl (1*S*,3*S*)-*rel*-3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate
CAS Registry Number		91465-08-6
Molecular Formula		$C_{23}H_{19}ClF_3NO_3$

Structural Formula





Molecular Weight 449.9

Registration Number	Purity of the Technical Grade Active Ingredient
24567	89.0%
29026	97.10%
30818	98%
31604	97.0%
31668	95.95%

Identity of relevant impurities of human health or environmental concern:

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure at 20°C	2×10^{-4} mPa
Ultraviolet (UV) / visible spectrum	No absorption maxima were found at $\lambda > 400$ nm.
Solubility in water at 20°C	0.005 mg/mL (pH 6.5)
n-Octanol/water partition coefficient at 20°C	Log Kow = 7
Dissociation constant	pKa > 9 (hydrolysis prevents measurement)

2.3 Description of Registered Lambda-cyhalothrin Uses

Appendix I lists all lambda-cyhalothrin products that are registered under the authority of the *Pest Control Products Act* as of January 2017. Appendix II lists all the commercial class uses for which lambda-cyhalothrin is presently registered. There are no Domestic Class end-use products. All current uses are being supported by the registrant and were, therefore, considered in the re-evaluation of Lambda-cyhalothrin.

Uses of lambda-cyhalothrin belong to the following use-site categories: greenhouse food crops, terrestrial non-food, non-feed and fibre crops, terrestrial feed and food crops, shelterbelts, turf, livestock, indoor and outdoor structural sites and surrounding soil, outdoor ornamentals, outdoor wasp and hornet nests.

3.0 Impact on Human And Animal Health

3.1 Toxicology Summary

The cyhalothrins are synthetic Type II pyrethroid insecticides, referred to as such due to the presence of an α-cyano group. The cyhalothrin molecule has three chiral centers and as a result, is comprised of eight distinct stereoisomers. Lambda-cyhalothrin is an equimolar mixture of four isomers, and cyhalothrin is comprised of all isomers. Due to similarity of structure, mode of action and qualitative toxicological findings as well as the inability to analytically distinguish the various isomeric mixtures, the human health risk assessment for lambda-cyhalothrin is based on the extensive toxicology database for cyhalothrin and lambda-cyhalothrin, including published papers in the scientific literature. The scientific quality of the available toxicology database is considered to be high.

It is noted that gamma-cyhalothrin, an enriched mixture of the two most insecticidally-active stereoisomers, is used in regulatory jurisdictions outside of Canada. As gamma-cyhalothrin is currently not registered at the PMRA, no toxicology data have been considered for this moiety. In the event that a submission for Canadian registration and/or specification of import MRL(s) is received, reference values for the cyhalothrins may have to be revisited.

Synthetic pyrethroids induce neurotoxic effects primarily by binding to voltage-dependant sodium channels in neurons, thereby delaying the closing of sodium channels and causing the depolarization of neurons. This affects action potentials and results in either repetitive activity (Type I pyrethroids) or blockage of nerve conduction (Type II pyrethroids). Type II pyrethroids, such as the cyhalothrins, typically induce the "CS syndrome" which is characterized by choreoathetosis (involuntary excessive movements progressing to sinuous writhing), sedation, salivation, dyspnoea, clonic seizures and tremors. Impairment of motor activity and acoustic startle response are also characteristic of Type II pyrethroids.

The cyhalothrins are highly lipophilic compounds, and thus, bioavailability and toxicity are significantly enhanced with digestible oils compared to aqueous vehicles. Available toxicokinetic data for the cyhalothrins are based on studies in which rats or dogs were treated orally with cyhalothrin or lambda-cyhalothrin either by capsule, gavage (in corn oil) or the diet, using various radioabels. Administration of a single oral dose in rats or dogs resulted in rapid but

incomplete absorption from the gastrointestinal tract (~50% in rats; ~80% in dogs). With increasing oral dose, absorption was slower and less extensive, with a greater proportion of the administered dose eliminated in feces. No difference in systemic exposure was noted between pregnant and non-pregnant rats treated by gavage with a single low dose of lambda-cyhalothrin.

Based on the results of radiolabel studies in which rats were administered a single oral dose, cyhalothrins are rapidly and extensively distributed, metabolized and eliminated, though high tissue levels and sex-related differences in the distribution and retention of radioactivity were noted in fat and gonads (notably ovary). The half-life for elimination of radioactivity from brown fat was 18 hours in males and 34 hours in females. Concentrations of radioactivity in peri-renal white fat, although initially lower than brown fat, did not decline markedly from their peak concentrations. The half-life in peri-renal white fat was in excess of the post-dosing period of 4 days in one study, and estimated to be 23 days in another study. Concentrations of radioactivity in the white fat of females were almost double that of males. The elimination half-lives in gonads were 7 hours for males (testes) and 25 hours for females (ovary). High concentrations of lambda-cyhalothrin were detected in all regions of the brain 3 hours post-dosing, with the highest concentrations detected in the hypothalamus. After 96 hours, levels of radioactivity remained highest in fat (brown/white fat) and ovary. A similar pattern of distribution and retention was noted following repeated oral exposure in rats to cyhalothrin for 14 days. Two days post-dosing, fatty tissue demonstrated significant accumulation of radioactivity (levels in white fat were up to 88-fold higher than blood). Lungs, liver, kidney and gonads also demonstrated concentrations of radioactivity which were 2- to 7-fold higher than levels in blood. Seven days after the last exposure, radioactivity levels declined significantly in the latter tissues, though levels remained higher than blood. Levels of radioactivity in white fat did not decline significantly 7 days following the last exposure, primarily due to the retention of the unchanged parent compound.

Following repeated oral exposure in rats to cyhalothrin for up to 119 days, peak levels of radioactivity were noted in most tissues by treatment day 70, while levels in fat increased up to day 119 (gonads were not assessed). Levels in fat declined slowly after cessation of exposure via first-order kinetics, with an elimination half-life of 31 days. Elimination from liver paralleled that of fat, likely due to the slow release of cyhalothrin from fat and redistribution to liver prior to elimination. The results of this study indicated that the cyhalothrins have the potential for bioaccumulation.

Based on the results of a rat developmental neurotoxicity study conducted with lambda-cyhalothrin, there was significant distribution of the unchanged parent compound to the mammary gland and to the neonate via maternal milk. Concentrations of unchanged parent compound in maternal plasma were proportional to maternal dietary intake, and were generally equivalent to levels in pup plasma throughout lactation.

Cyhalothrin and lambda-cyhalothrin were extensively metabolized by hydrolysis of the ester bond. Major metabolites were similar for both compounds, and included cyclopropylcarboxylic acid and its glucuronide conjugate, 3-phenoxybenzoic acid (3-PBA) and 3-(4'-hydroxyphenoxy) benzoic acid and its sulphate conjugate.

Administration of a single or repeated oral dose of the cyhalothrins in rats or dogs resulted in rapid elimination in both species and sexes, with approximately 85% to 90% of the administered dose eliminated within 72 hours. Elimination occurred primarily via feces (as unchanged parent compound) and to a lesser extent via urine. Unabsorbed material was eliminated in feces as unchanged parent compound. Unchanged parent compound was not identified in urine, bile or expired air.

Acute oral toxicity studies in rodents conducted with cyhalothrin or lambda-cyhalothrin indicated moderate toxicity in aqueous vehicle and high toxicity in oil. Clinical signs of toxicity following acute exposure to cyhalothrin or lambda-cyhalothrin were consistent with Type II pyrethroids and included salivation, motor incoordination, signs of paresthesia, splayed limbs, tremors, clonic convulsions, hunched back and tip-toe gait. In acute dermal studies, lambda-cyhalothrin was of low to moderate toxicity in rats when administered in aqueous suspension or undiluted, and induced clinical signs of neurotoxicity at high doses. Particulate or aerosolized lambda-cyhalothrin produced moderate acute inhalation toxicity following nose-only exposure in rats. In rabbits, lambda-cyhalothrin produced mild eye irritation, and slight dermal irritation when administered undiluted. Lambda-cyhalothrin was not a dermal sensitizer when administered in oil in the Maximisation Test or the Local Lymph Node Assay. No significant sex-related differences in acute toxicity were noted for either form of the test material used.

Based on the results of repeat-dose oral toxicity studies, the dog is the most sensitive species to the effects of cyhalothrin or lambda-cyhalothrin. The most sensitive indicators of toxicity were signs of neurotoxicity, liquid feces and decreased testes weights in dogs treated orally (by capsule) with lambda-cyhalothrin for one year. Liquid feces were also noted in acute dermal studies in rats treated with lambda-cyhalothrin, and at low oral doses in three subchronic studies in dogs conducted with lambda-cyhalothrin or cyhalothrin. Mortality, decreased body weight, severe neurotoxic signs, decreased brain weight and signs of paresthesia were observed in dogs and rodents treated with higher oral doses. Other notable effects at higher oral doses in repeat-dose studies included ovarian and testicular effects in all species, hematological changes in rodents and rabbits, decreased plasma cholesterol and liver effects in rodents and dogs, and degenerative renal histopathology in rats. No sex-related differences in sensitivity were noted in repeat-dose oral studies, despite the greater retention of cyhalothrin in the adipose and reproductive tissues of female rats in toxicokinetic studies, compared to males.

In rats, short-term nose-only inhalation exposure to lambda-cyhalothrin aerosol produced clinical signs of neurotoxicity, reduced body weight, liver effects, decreased plasma cholesterol and punctate foci in the cornea at the lowest effect level, with more severe neurological signs, organ weight changes and hematological effects at higher concentrations.

Short-term dermal exposure in rats to lambda-cyhalothrin in oil produced similar systemic effects as those noted following oral or inhalation exposure, including signs of neurotoxicity, decreased body weight, effects on reproductive organs (decreased ovary weights, atrophy of seminal vesicles), decreased plasma cholesterol and signs of paresthesia (characterized as upward curvature of the spine).

Systemic effects were also noted in abraded and non-abraded rabbits treated dermally with cyhalothrin in polyethylene glycol (PEG), including decreased body weight, decreased gonad weights and clinical signs of neurotoxicity. In addition, dermal effects including desquamation, erythema, wrinkling, cracking and scabbing were observed in non-abraded and abraded rabbits treated with cyhalothrin in this study.

In neurotoxicity studies and standard repeat-dose toxicity studies conducted by the oral, dermal or inhalation routes of exposure, cyhalothrin and lambda-cyhalothrin induced neurological effects in all species tested (rodents, dogs, rabbits). Effects were consistent with Type II pyrethroids, including mortality, decreased body weight, salivation, piloerection, decreased motor activity, splayed hindlimbs, impaired gait, hunched posture, hypersensitivity to touch and sound, tremors and convulsions. Decreased motor activity was the most sensitive endpoint of toxicity in acute oral neurotoxicity studies conducted in rats (lambda-cyhalothrin in corn oil). In subchronic oral neurotoxicity studies conducted in rats with cyhalothrin or lambda-cyhalothrin, altered FOB parameters and increased corticosterone levels were the most sensitive effects, with liquid feces, decreased body weight and neurotoxic signs noted at higher oral doses. Decreased absolute brain weight was observed in repeat-dose oral studies conducted in mice and rats, though at exposure levels which were greater than those producing clinical signs of neurotoxicity. There was no clear evidence of neuropathology in any species tested, and no evidence of delayed neurotoxicity in hens. Throughout the database for cyhalothrin and lambda-cyhalothrin, signs of paraesthesia (that is, upward curvature of the spine, biting and chewing of extremities, repetitive grooming, dermal wounds) were evident and were considered an acute effect, distinct from irritation.

Serious effects in the young were noted in a developmental neurotoxicity (DNT) study and two range-finding DNT studies conducted in rats exposed orally to lambda-cyhalothrin. In offspring in the main DNT study, reductions were noted in pup survival, body weight and litter weight, as well as impaired learning and memory, decreased brain morphometric measurements and decreased auditory startle response. These findings were noted in the presence of reduced maternal body weight. This study was considered a non-guideline study, however, owing to the limited assessment of offspring toxicity, including inadequate motor activity and auditory response data (that is, lack of habituation), lack of brain morphometric data at the mid- and low-doses, and inappropriate statistical analysis of body weight, brain weight and brain morphometric data. In the range-finding DNT studies, decreased pup survival and increased missing or presumed dead pups were observed in the absence of maternal toxicity following dietary administration of lambda-cyhalothrin to dams. At slightly higher oral doses in the range-finding studies, increased total litter loss and decreased pup body weight were also observed in the presence of reduced maternal body weight and clinical signs of toxicity.

Pyrethroid neurotoxicity is generally correlated with the peak concentration of unchanged parent compound, and it has been established that the design of a DNT study does not consider time-to-peak-effect and thus may miss the window of peak toxicity for the pyrethroids. It is known that the metabolic clearance of pyrethroids in rats increases during maturation, primarily due to increased hepatic enzyme activity. Incomplete maturation of enzyme systems in the liver which detoxify pyrethroids may result in increased pyrethroid concentrations in target tissues (that is, the brain) and increased susceptibility of the young to toxicity, compared to adults receiving the same oral dose. Given the limitations of the DNT study design in this regard, an adequate

comparison of the relative sensitivity of the young animal to the adult is currently not available. A comparative oral gavage neurotoxicity study conducted in pups, weanling and adults, which considers the time-to-peak effect, could address this uncertainty. The PMRA is aware that there is currently work underway by a consortium of pyrethroid registrants to develop data to help address issues of comparative sensitivity of young and adult animals to pyrethroid neurotoxicity. The PMRA will consider this information when the studies become available. In the interim, this uncertainty has been reflected in the form of a database uncertainty factor.

The results of genotoxicity studies conducted with cyhalothrin and lambda-cyhalothrin were mixed, with some positive results observed in vitro and in vivo. Lambda-cyhalothrin as well as formulations containing this active ingredient have been shown to produce oxidative stress and decreased antioxidant enzyme activities in various tissues in rats (liver, kidney, brain, testes) and rabbits (testes) treated orally in short-term studies, which may contribute to the potential for DNA damage.

In in vitro studies, cyhalothrin was positive for induction of cell transformation in hamster kidney cells in a supplemental study and negative for induction of reverse mutation in bacteria. In the only in vivo study identified for cyhalothrin, negative results were observed for induction of dominant lethal mutation in mice.

In in vitro studies conducted with lambda-cyhalothrin, positive results were noted for DNA damage in mouse macrophages in an adequate study, and chromosomal aberrations in human lymphocytes in a supplemental assay. In other in vitro studies, lambda-cyhalothrin was negative for reverse mutation in bacteria, forward mutation in mouse lymphoma cells, clastogenicity in rat lymphocytes and unscheduled DNA synthesis in rat hepatocytes in adequate studies, and chromosomal aberrations in human lymphocytes in a supplemental assay. In in vivo studies, lambda-cyhalothrin was positive for DNA damage in rat hepatocytes and lymphocytes, and chromosomal aberrations in rat lymphocytes. Additional positive results were obtained in 5 supplemental studies (most conducted with formulated cyhalothrin) assessing chromosome aberrations in rat and mouse bone marrow cells and mouse spermatocytes, sister chromatid exchange in mouse bone marrow, micronuclei in rat bone marrow and gut epithelium, DNA damage in rat gut epithelium and altered sperm morphology in rats. Negative results were noted in vivo for induction of dominant lethal mutation in mice, micronuclei in mouse bone marrow cells and chromosomal aberrations in rat bone marrow cells in adequate studies with lambda-cyhalothrin.

In female mice, treatment in the diet for 104-weeks with cyhalothrin produced an increase in the incidence of mammary adenocarcinomas, and an increase in the combined incidence of uterine leiomyomas and leiomyosarcomas. These tumors had a positive test for trend, incidences which exceeded concurrent controls, and incidences which exceeded or were at the top of the range for historical controls. In view of this evidence, the mammary and uterine tumors in mice were considered to be treatment-related. In female rats treated in the diet with cyhalothrin for 104-weeks, there was an increase in the incidence of mammary fibroadenomas. These tumors were considered to be equivocal, however, due to poor dose-response and lack of statistical significance in pair-wise tests.

There was evidence of female (and male) reproductive toxicity throughout the database, high deposition and retention of the cyhalothrins in female (and male) reproductive tissues, increased secretory activity of the mammary gland in the rat chronic dietary study and evidence of endocrine toxicity in vitro and in vivo. Moreover, the significant distribution of the cyhalothrins to rat mammary gland, based on studies which demonstrate unchanged parent compound in maternal plasma and milk and pup plasma during the lactation period, suggest the mammary gland may be a target. It is also noteworthy that treatment-related tumors were reported in female mice in several studies conducted with structurally-similar pyrethroids (though different tissues were affected), and there is evidence of genotoxicity in in vitro and in vivo studies. Based on the weight of evidence, lambda-cyhalothrin is considered to have carcinogenic potential, and as such, a quantitative cancer risk assessment was undertaken.

Lambda-cyhalothrin is not among the group of pesticide active ingredients to be screened under the United States Environmental Protection Agency (USEPA) Endocrine Disruptor Screening Program. However, the results of published and unpublished studies indicate that the cyhalothrins have the potential to interact with androgen and estrogen hormone systems. While several literature studies were conducted with end-use formulations containing lambda-cyhalothrin or aqueous cyhalothrin of unknown purity, the information is considered useful in the assessment of weight of evidence for endocrine effects of the cyhalothrins. Short-term oral administration of lambda-cyhalothrin in rabbits decreased plasma testosterone levels, and short-term oral administration of cyhalothrin in rats increased serum corticosterone levels. Effects on hormone levels were noted in dams and offspring following short-term gavage administration of lambda-cyhalothrin formulation in pregnant rats. Decreased serum T3 and T4 levels and increased serum TSH levels were observed in dams throughout gestation, and dams and their offspring throughout lactation. Effects on thyroid hormone production were supported by the results of in vitro studies in which cyhalothrin and its metabolite 3-PBA demonstrated thyroid receptor binding antagonistic activity in a receptor-mediated reporter gene assay in CV-1 cells.

Other endocrine-related effects in females included mammary and uterine tumors in chronic dietary rodent assays and ovarian effects in all species tested (mice, rats, dogs, rabbits, hens). Reduced ovary weights were noted in the mouse, rat and dog in repeat-dose oral studies. Evidence of ovarian macroscopic changes (cysts, nodules) in rabbits and hens treated orally with cyhalothrin and decreased ovary weights in rats and rabbits exposed dermally to lambda-cyhalothrin or cyhalothrin were also observed. In published literature studies, cyhalothrin displayed weak estrogenic activity in an in vitro estrogen receptor competitive binding assay in CV-1 cells, increased cellular proliferation in human breast carcinoma cells, produced positive results using the pS2 gene expression assay, decreased estrogen receptor gene expression and increased progesterone receptor mRNA expression in human breast carcinoma cells.

Endocrine-related effects in males included treatment-related functional and morphological changes in the testes, which were consistently noted throughout the database in several species (mice, rats, dogs, rabbits) and with multiple routes of exposure (oral, dermal). There were reduced testes weights in oral studies conducted with rodents and dogs, with testicular effects in dogs noted at doses which were within the range of critical effect levels used for risk assessment purposes. Tubular degeneration and calcification of the testes were noted at the highest dose tested in the chronic rat dietary study with cyhalothrin. In short-term dermal studies, seminal vesicle atrophy was observed in rats treated with lambda-cyhalothrin, and decreased gonad

weights were noted in rabbits treated with cyhalothrin. Supplementary data in pregnant rats treated dermally with aqueous cyhalothrin suggest that testicular effects can be induced with in utero exposure, in the absence of maternal toxicity. In specialized studies of male reproductive effects, decreased testes weights, degenerative histopathology in the testes, abnormal sperm morphology, decreased sperm count, motility and viability, increased semen lipid peroxidation, increased dead sperm, decreased testicular antioxidant enzyme activities, decreased semen volume, decreased plasma testosterone levels and decreased libido were noted in male mice, rats or rabbits exposed orally to technical grade or formulated lambda-cyhalothrin.

There was no evidence of adverse effects on mating performance or fertility in a dietary multi-generation reproductive toxicity study in rats conducted with cyhalothrin although this investigation lacked estrus cycle and sperm measurements. Effects in parental animals were similar to those in repeat-dose oral toxicity studies (that is, decreased body weight) and were evident at dose levels which were similar to those noted in non-pregnant females. There was some evidence of sensitivity of the young in this study, with decreased body weight in offspring during the lactation phase observed in the absence of maternal toxicity. Pups were likely exposed to cyhalothrin during the lactation phase, based on the demonstration of significant distribution of lambda-cyhalothrin to maternal milk in the rat dietary DNT study. Given that a full assessment of reproductive function was not conducted in the existing reproductive toxicity study, there exists some uncertainty regarding the point of departure for reproductive effects, in view of the endocrine-related effects noted with the cyhalothrins. This is particularly the case for assessing the effects of the cyhalothrins on testicular function and morphology in young and adult animals (that is, to define the point of departure for testicular toxicity). This uncertainty is addressed through the application of a database uncertainty factor.

In guideline developmental toxicity studies, cyhalothrin did not produce developmental toxicity in rats or rabbits following gavage administration in oil at maternally-toxic doses. At the lowest effect levels, signs of toxicity in dams included decreased body weight, loss of limb coordination and perioral and/or abdominal soiling, with additional clinical signs (including head rocking side to side, agitation, resistance to handling) at higher oral doses. In supplementary studies, however, delayed ear opening, eye opening, fur development and age of testes descent were observed in the absence of maternal toxicity in rats treated dermally with aqueous cyhalothrin. Delayed eye opening and ear detachment were also noted in the offspring of rats treated by gavage during gestation and lactation with lambda-cyhalothrin formulation in saline.

The toxicology endpoints used in PMRA's human health risk assessment of lambda-cyhalothrin are summarized in Appendix III, Table 1. A summary of the toxicology studies conducted on laboratory animals with the cyhalothrins is presented in Appendix III, Table 2.

3.1.1 *Pest Control Products Act* Hazard Considerations

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor (PCPA factor) to take into account the completeness of the data with respect to the exposure of, and toxicity to, infants and children as well as potential pre- and post-natal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicology database for the assessment of risk to infants and children, the standard complement of required studies for risk assessment were available including oral developmental toxicity studies in rats and rabbits and a multi-generation reproductive toxicity study in rats. A non-guideline DNT study in rats (with limited assessment of offspring toxicity) and supplemental range-finding DNT studies in rats were also available.

With respect to concerns relevant to the assessment of risk to infants and children, there was no evidence of increased susceptibility of the young to in utero exposure in guideline oral developmental toxicity studies conducted in rats or rabbits. There was some evidence of sensitivity of the young in a multi-generation reproductive toxicity study in rats, with decreased body weight observed in offspring in the absence of maternal toxicity. Moreover, serious neurological effects were noted in offspring in a non-guideline oral DNT study in rats, as characterized by impaired learning and memory, decreased auditory startle response and brain morphometric changes at a dose which produced reduced maternal body weights only. There was also evidence of serious effects in offspring (decreased pup survival, increased number of missing/presumed dead pups) in the absence of maternal toxicity in an oral range-finding DNT study conducted with lambda-cyhalothrin in rats.

Young animals have incomplete maturation of enzyme systems which detoxify pyrethroids and thus may be more susceptible due to higher and prolonged brain concentrations, compared to adults. Due to the lack of a comparative oral neurotoxicity study, an adequate assessment of sensitivity of the young is currently not available and residual uncertainty remains concerning susceptibility of the young to potential neurotoxic effects. This concern was reflected through the use of a database uncertainty factor of 3-fold. In addition, a 3-fold database uncertainty factor was applied due to lack of information regarding the point of departure for testicular toxicity. Where both of these concerns were identified, only one 3-fold factor was applied for risk assessment purposes. Since concerns were addressed with a database uncertainty factor, the PCPA factor was reduced to 1-fold.

3.2 Dietary Exposure and Risk Assessment

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in milk and meat, may be ingested with the daily diet. Exposure to lambda-cyhalothrin from potentially treated imported foods is also included in the assessment. These dietary assessments are age-specific and incorporate the different eating habits of the population at various stages of life (infants, children, adolescents, adults and seniors). For example, the assessments take into account differences in children's eating patterns, such as food preferences and the greater consumption of food relative to their body weight when compared to adults. Dietary risk is then determined by the combination of the exposure and the toxicity assessments. High toxicity may not indicate high risk if the exposure is low. Similarly, there may be risk from a pesticide with low toxicity if the exposure is high.

The PMRA considers limiting use of a pesticide when dietary exposure exceeds 100% of the reference dose or the lifetime cancer risk estimate exceeds 1×10^{-6} (one-in-a-million). PMRA's Science Policy Note SPN2003-03, *Assessing Exposure from Pesticides, A User's Guide*, presents detailed acute, chronic and cancer risk assessment procedures.

Residue estimates used in the dietary risk assessment may be based conservatively (using upper bound estimates) on the maximum residue limits (MRL) or field trial data representing the residues that may remain on food after treatment at the maximum label rate. Monitoring data representative of the national food supply may also be used to derive a more accurate estimate of residues that may remain on food when it is purchased. These include the Canadian Food Inspection Agency's (CFIA) National Chemical Residue Monitoring Program and the United States Department of Agriculture's (USDA) Pesticide Data Program (PDP). Theoretical and experimental processing factors, as well as specific information regarding percent of crops treated may also be incorporated to the greatest extent possible.

In situations where the need to mitigate dietary exposure has been identified, the following options are considered. Dietary exposure from Canadian agricultural uses can be mitigated through changes in the use pattern. Revisions of the use pattern may include such actions as reducing the application rate or the number of seasonal applications, establishing longer pre-harvest intervals, and/or removing uses from the label. In order to quantify the impact of such measures, new residue chemistry studies that reflect the revised use pattern would be required. These data would also be required in order to amend MRLs to the appropriate level. Imported commodities that have been treated also contribute to the dietary exposure and are routinely considered in the risk assessment. The mitigation of dietary exposure that may arise from treated imports is generally achieved through the amendment or specification of MRLs.

Sufficient information was available to adequately assess the dietary exposure and risk of lambda-cyhalothrin. Acute, chronic and cancer dietary exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model - Food Commodity Intake Database™ (DEEM-FCID™; Version 4.02, 05-10-c) program, which incorporates food consumption data from the National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) 2005-2010 available through the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS).

The acute and chronic/cancer dietary exposure estimates for lambda-cyhalothrin are considered to be highly refined (more precise) as monitoring data, percent crop treated (PCT), experimental processing factors and domestic/import data were used to the extent possible. There is, however, an uncertainty associated with the import residues used in this assessment because the enforcement methods for plant and animal commodities do not distinguish between lambda- and gamma-cyhalothrin. Specifically, while gamma-cyhalothrin is currently not registered in Canada, it is registered for use in the United States and other countries, and it has been identified internationally as being more toxic than lambda-cyhalothrin. Therefore, while the risk estimates may underestimate exposure from imported commodities treated with gamma-cyhalothrin, the current assessments have retained a certain level of conservatism due to the use of MRLs/tolerances or anticipated residues (from field trials) for certain commodities. However, in the event that a submission for Canadian registration and/or specification of import MRL(s) is received for gamma-cyhalothrin, reference values and the corresponding risk assessments for the cyhalothrins may have to be re-visited. For more information on dietary risk estimates or residue chemistry information used in the dietary assessment, see Appendices IV and V, respectively.

3.2.1 Determination of Acute Reference Dose (ARfD)

To estimate acute dietary risk, the $BMDL_{20}$ of 0.19 mg/kg bw from an acute oral neurotoxicity study conducted with lambda-cyhalothrin was selected, based on reduced motor activity in adult rats. Reduced motor activity was considered the critical endpoint since it is a sensitive neurobehavioral endpoint relevant to pyrethroid toxicity and was derived in a study conducted by a relevant route and duration of exposure. The $BMDL_{20}$ was specifically selected based on the reported variability of motor activity in control rats in the literature. Since there is concern that the critical endpoint in adults may not be adequate for assessment of the young, a 3-fold database uncertainty factor was applied for risk assessment purposes. Consequently, the PCPA factor was reduced to 1-fold as discussed in the *Pest Control Products Act* Hazard Considerations Section. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were also applied, resulting in a composite assessment factor (CAF) of 300.

$$\text{ARfD} = \frac{\text{BMDL}_{20}}{\text{CAF}} = \frac{0.19 \text{ mg/kg bw}}{300} = 0.0006 \text{ mg/kg bw}$$

3.2.2 Acute Dietary Exposure and Risk Assessment

The acute dietary risk (from food and drinking water) was calculated considering the highest ingestion of lambda-cyhalothrin residues that would be likely on any one day, and using food consumption and food residue values. The expected intake of residues is compared to the ARfD, which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the expected intake of residues is less than the ARfD, the acute dietary exposure is not of concern.

The acute probabilistic risk assessment was conducted using available CFIA and PDP monitoring data. MRLs/tolerances or anticipated residues (from field trials) were used for a few commodities for which no monitoring data were available. In addition, the following inputs were used: available PCT information in Canada and in the US; 100% crop treated for commodities for which no PCT information was available; available information on domestic production and import supply; and available experimental processing factors. DEEM-FCID default processing factors were used when experimental processing factors were not available. Drinking water contribution to the exposure was accounted for by direct incorporation of the highest estimated environmental concentration (EEC), obtained from water modelling (see Section 3.3), into the dietary exposure evaluation model (DEEM-FCID).

The acute exposure estimates at the 99.9^{th} percentile for the general population and all subpopulations range from 364% to 913% of the ARfD, and therefore are of concern. No specific major risk drivers were identified as the acute risk is driven by exposure from multiple commodities. Drinking water contribution to the acute exposure is very low, accounting for less than 1% of the total dietary exposure.

3.2.3 Determination of Acceptable Daily Intake (ADI)

To estimate risk from repeated dietary exposure, a NOAEL of 0.1 mg/kg bw/day was selected based on neurotoxic signs, liquid feces and decreased relative testes weights in dogs treated orally (via capsule) with 0.5 mg/kg bw/day lambda-cyhalothrin for 12 months. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. Residual uncertainty regarding potential susceptibility of the young and inadequate assessment of male reproductive function was addressed via the application of a 3-fold database uncertainty factor. The PCPA factor was reduced to 1-fold, as discussed in the *Pest Control Products Act* Hazard Considerations Section. Therefore, the CAF was 300.

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{0.1 \text{ mg/kg bw/day}}{300} = 0.0003 \text{ mg/kg bw/day}$$

The ADI provides a margin of 16,333 to the NOAEL for offspring effects (4.9 mg/kg bw/day) in the oral DNT study in rats.

3.2.4 Chronic Dietary Exposure and Risk Assessment

The chronic dietary risk (from food and drinking water) was calculated by using the average consumption of different foods and the average residue values on those foods. This estimated exposure was then compared to the ADI. When the estimated exposure is less than the ADI, the chronic dietary exposure is not of concern.

The chronic assessment was conducted using average residues from the same CFIA and PDP monitoring data used in the acute assessment, adjusted with percent crop treated data and domestic/import statistics; anticipated residues (from field trials) for commodities for which no monitoring data were available; MRLs/tolerances for commodities for which no monitoring data or anticipated residues were available; experimental processing factors when available (otherwise DEEM-FCID default processing factors were used); and the chronic drinking water EEC point estimate obtained from modelling (see Section 3.3).

The chronic exposure estimates for the general population and all subpopulations range from 40% to 115% of the ADI, and therefore are of concern. No specific major risk drivers were identified as the chronic risk is driven by exposure from multiple commodities. Drinking water contribution to the chronic exposure is very low, accounting for less than 1% of the total dietary exposure.

3.2.5 Cancer Assessment

The cyhalothrins are considered to have carcinogenic potential based on the weight of evidence. There was evidence of a treatment-related increase in mammary adenocarcinomas and uterine leiomyomas/leiomyosarcomas in female mice treated with cyhalothrin, equivocal evidence of an increased incidence of mammary fibroadenomas in female rats treated with cyhalothrin, and evidence of genotoxicity based on the outcome of in vitro and in vivo studies.

In addition, exposure to cyhalothrin or lambda-cyhalothrin produced effects on the endocrine system both in vitro and in vivo, and resulted in high deposition and retention of cyhalothrin in male and female reproductive organs. Moreover, there is evidence of carcinogenicity in female mice following exposure to structurally-related pyrethroids (though different tissues were affected).

The potential roles of oxidative stress, cytotoxicity, proliferation and induction of DNA damage are unclear, and thus insufficient mode of action data are available at this time to support a threshold approach. For this reason, a linear low-dose extrapolation approach for cancer risk assessment was adopted. Incidence data for mammary adenocarcinomas in mice resulted in poor model fit during linear extrapolation, and thus were not selected for quantitative cancer risk assessment. Therefore, a cancer potency estimate (q_1^*) of 2.66×10^{-2} (mg/kg bw/day)$^{-1}$ was derived based on the combined incidence of uterine leiomyomas and leiomyosarcomas in female mice treated with cyhalothrin; this estimate is considered protective of the mammary adenocarcinomas in mice and the equivocal mammary fibroadenomas in rats.

3.2.6 Cancer Dietary Exposure and Risk Assessment

The cancer dietary risk (from food and drinking water) was conducted for the general population by using the same chronic residues as described in Section 3.2.4. The estimated chronic exposure was then compared to the cancer potency factor (q_1^*) to determine the lifetime cancer risk. A lifetime cancer risk that is equal or less than 1×10^{-6} (one-in-a-million) usually does not indicate a risk of concern for the general population when exposure occurs through pesticide residues in or on food and drinking water, or to otherwise unintentionally exposed persons.

Based on the q_1^* approach, the lifetime cancer risk estimate from dietary exposure is 5×10^{-6} for the general population, and therefore is of concern. No specific major risk drivers were identified as the cancer risk is driven by exposure from multiple commodities. Drinking water contribution to the lifetime exposure is very low, accounting for less than 1% of the total dietary exposure.

3.3 Exposure from Food and Drinking Water

Residues of lambda-cyhalothrin in potential drinking water sources were estimated from modelling using the typical use rate for turf, which represent the highest registered outdoor broadcast application rate in Canada.

3.3.1 Concentrations in Drinking Water

Estimated Concentrations in Drinking Water Sources: Level 1 Modelling
Estimated environmental concentrations (EECs) of lambda-cyhalothrin in potential drinking water sources (groundwater and surface water) were generated using computer simulation models. EECs of lambda-cyhalothrin in groundwater were calculated using the PRZM-GW model to simulate leaching through a layered soil profile over a 50-year period. The concentrations calculated using PRZM-GW are average concentrations in the top 1 m of the water table.

EECs of lambda-cyhalothrin in surface water were calculated using the SWCC model, which simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. Pesticide concentrations in surface water were estimated in a vulnerable drinking water source, a small reservoir.

A Level 1 drinking water assessment was conducted using conservative assumptions with respect to environmental fate, application rate and timing, and geographic scenario. The Level 1 EEC estimate is expected to allow for future expansion to additional non-food uses. Table 1 in Appendix VII lists the application information and main environmental fate characteristics used in the simulations. A number of initial application dates between May and September were modelled. The model was run for 50 years for all scenarios. The largest EECs of all selected runs are reported in Table 2 in Appendix VII.

The highest daily surface water EEC value of 0.0012 ppm for lambda-cyhalothrin was used in the acute dietary exposure assessment. The highest yearly surface water EEC value of 0.00013 ppm was used in the chronic and cancer exposure assessments.

3.3.2 Drinking Water Exposure and Risk Assessment

Drinking water exposure estimates were combined with food exposure estimates, with EEC point estimates incorporated directly in the dietary (food + drinking water) assessments. Refer to Sections 3.2.2, 3.2.4, and 3.2.6.

3.4 Occupational and Non-Occupational Exposure and Risk Assessment

Occupational and non-occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

3.4.1 Toxicology Endpoint Selection for Occupational and Non-Occupational Risk Assessment

Short-, Intermediate- and Long-Term Dermal Exposure:
For short-, intermediate- and long-term dermal risk assessment in all populations, a NOAEL of 10 mg/kg bw/day was selected based on neurotoxic effects, decreased body weight, decreased relative ovary weight and atrophy of the seminal vesicles at the LOAEL of 50 mg/kg bw/day in a 21-day dermal rat study with lambda-cyhalothrin. A target Margin of Exposure (MOE) of 300 was derived for the critical endpoint. This includes uncertainty factors of 10-fold for interspecies extrapolation, 10-fold for intraspecies variability and a 3-fold database uncertainty factor for concerns related to sensitivity of the young and inadequate assessment of male reproductive function. For residential scenarios, the PCPA factor was reduced to 1-fold as discussed in the *Pest Control Products Act* Hazard Considerations Section.

Short-, Intermediate- and Long-Term Inhalation:
The most appropriate study for short-, intermediate- and long-term inhalation risk assessment in all populations is the short-term (nose-only) inhalation toxicity study in 8-week old rats in which a NOAEL of 0.08 mg/kg bw/day (0.3 µg/L) for lambda-cyhalothrin was derived based on reduced body weight, neurotoxic signs, increased liver weight, decreased plasma cholesterol and punctate foci of the cornea at the LOAEL of 0.9 mg/kg bw/day. This NOAEL was selected as it is based on an appropriate route of exposure and is protective of other systemic and neurological effects. A target MOE of 300 was selected, which includes 10-fold for interspecies extrapolation, 10-fold for intraspecies variability and a 3-fold database uncertainty factor for concerns related to sensitivity of the young and inadequate assessment of male reproductive function. For residential scenarios, the PCPA factor was reduced to 1-fold as discussed in the *Pest Control Products Act* Hazard Considerations Section.

Short- and Intermediate-Term Non-Dietary Incidental Oral Ingestion:
For assessment of short- and intermediate-term non-dietary (incidental) oral exposure, the $BMDL_{20}$ of 0.19 mg/kg bw from an acute oral neurotoxicity study conducted with lambda-cyhalothrin was selected, based on reduced motor activity in adult rats. A target MOE of 300 was selected which includes 10-fold for interspecies extrapolation, 10-fold for intraspecies variability and a 3-fold database uncertainty factor for concerns related to sensitivity of the young. The PCPA factor was reduced to 1-fold as discussed in the *Pest Control Products Act* Hazard Considerations Section.

Cancer Potency Factor:
A cancer potency factor of 2.66×10^{-2} $(mg/kg\ bw/day)^{-1}$ was derived based on the combined incidence of uterine leiomyoma and leiomyosarcoma in female mice treated orally with cyhalothrin. See Section 3.2.5.

Dermal Absorption:
A dermal absorption factor was not required for the non-cancer short-, intermediate-, and long-term exposure risk assessment, as the toxicological endpoint selected was based on a dermal toxicity study. However, a dermal absorption value was required in estimating cancer risk, as the cancer potency estimate was based on an oral study. Using a weight-of-evidence approach, the results of the human and rat *in vivo* studies were considered in conjunction with the physical/chemical properties of lambda-cyhalothrin and observations from the toxicological studies, to select a dermal absorption value of 14%.

3.4.2 Non-Occupational Exposure and Risk Assessment

Non-occupational (residential) risk assessment involves estimating risks to the general population, including youth and children, during or after pesticide application.

The United States Environmental Protection Agency (USEPA) has generated standard default assumptions for developing residential exposure assessments for both applicator and postapplication exposures when chemical- and/or site-specific field data are limited. The assumptions and algorithms may be used in the absence of, or as a supplement to, chemical- and/or site-specific data and generally result in high-end estimates of exposure. The assumptions and algorithms relevant to the lambda-cyhalothrin re-evaluation are outlined in the Standard

Operating Procedures (SOPs) for Residential Pesticide Exposure Assessments 2012 under "Section 3: Lawns and Turf", "Section 4: Gardens and Trees", and "Section 7: Indoor Environments".

3.4.2.1 Residential Handler Exposure and Risk Assessment

There are no domestic-class products containing lambda-cyhalothrin. Therefore, a residential applicator/handler assessment was not conducted.

3.4.2.2 Residential Postapplication Exposure and Non-Cancer Risk Assessment

Residential postapplication exposure occurs when an individual is exposed through dermal, inhalation and/or incidental oral (non-dietary ingestion) routes as a result of being in a residential environment that has been previously treated with a pesticide. For lambda-cyhalothrin, the residential areas may be treated by a commercial applicator hired to treat the area.

Indoor Uses:

For indoor structural applications, the following postapplication scenarios from surface-directed applications were assessed: band and spot application, bedbug application, and crack and crevice application. Two formulation types were assessed for indoor uses: liquid formulations (for example, microcapsule suspension, emulsifiable concentrate) or pressurized products (aerosols). As per the USEPA Residential SOPs, in the absence of adequate chemical-specific data, different inputs (for example, amount of deposited residues) were used for the different formulations. Multiple applications were not assessed, since exposure on the day of application, without any dissipation, was assumed for the entire duration of exposure. This is considered to be a conservative assumption (resulting in upperbound estimates of exposure), combined with the other inputs and algorthims from the USEPA Residential SOPs.

Postapplication residential exposure to lambda-cyhalothrin is generally expected to be short- to intermediate-term (that is, from 1 day to several months) in duration, with the exception of bedbug treatments for which the duration could be long-term (that is, 6 months or longer).

The following lifestages and routes of exposure were assessed:

- Adults, youth, and children (1 to <2 years old) dermal and inhalation exposure
- Children (1 to <2 years old) incidental oral (hand-to-mouth) exposure

The calculated MOEs from inhalation exposure were greater than the target MOE for all lifestages for all scenarios, and therefore inhalation risks are not of concern (Appendix VII, Table 1).

The calculated MOEs from dermal exposure for the short- to intermediate-term duration was less than the target MOE for all lifestages for all scenarios, except crack and crevice application (see Appendix VII, Tables 2-3). Since risks were identified for the shorter duration of exposure, risks from long-term duration of dermal exposure for bedbug application were not determined.

For short- to intermediate-term hand-to-mouth exposure, target MOEs were not met for all scenarios including crack and crevice application, and therefore there are risks of concern for children (see Appendix VII, Tables 6-8). A long-term hand-to-mouth exposure assessment was not conducted, as risks of concern were identified for the short- to intermediate-term risk assessment. For the same reason, an object-to-mouth risk assessment was not considered.

Combined exposures and risk from dermal and inhalation exposure to adults and youth were conducted for crack and crevice applications. Target MOEs were met and therefore, risk is not of concern (see Appendix VIII, Tables 9-10).

Since risks of concern were identified for hand-to-mouth exposures for children for all scenarios, including crack and crevice applications, application of lambda-cyhalothrin in indoor residential areas is proposed for cancellation. In non-residential areas, crack and crevice applications are permitted, while band and spot application, and bedbug application will be cancelled. Proposed label directions will include definitions of residential and non-residential areas, as well as the definition and specific use instructions for crack and crevice applications, as follows:

Residential areas are defined as any use site where the general public, including children, could be exposed during or after application. For structural uses, in residential sites, this includes homes, schools, restaurants, public buildings or any other areas where the general public including children may potentially be exposed. Non-residential areas include, but are not limited to: industrial/commercial indoor sites (for example, laboratories, warehouses, food granaries); modes of transport in areas where passengers are not present (for example, buses, railcars, trailers); and animal housing (for example, livestock housing and poultry, pet kennels).

Crack and crevice is defined as an application of pesticides with the use of a pin stream nozzle, into cracks and crevices in which pests hide or through which they may enter a building. It does not permit the treatment of surfaces. Such openings commonly occur at expansion joints, between different elements of construction, and between equipment and floors. These openings may lead to voids such as hollow walls, equipment legs and bases, conduits, motor housings, or junction or switch boxes. To ensure crack and crevice application only, revised label directions must specify that the product can only be applied using low pressure sprayer equipment with a pin stream nozzle to direct sprays into cracks and crevices.

Outdoor Uses:

Outdoor residential uses include garden and tree applications, and lawn/turf application. Turf applications include application to golf courses, and to residential and non-residential lawns. All outdoor applications use liquid formulations only.

Postapplication dermal exposure using activity-specific transfer coefficients (TCs) was calculated using estimates for transferable residue or dislodgeable foliar residue, turf- or leaf-to-skin residue transfer for individuals contacting treated turf or foliage during certain activities, and exposure time. A TC is a factor that relates exposure to trasnferable or dislodgeable residues.

It is the amount of treated surface that a person contacts while performing activities in a given period (usually expressed in units of cm^2 per hour) and is specific to a particular lifestage. For the residential postapplication assessment of lambda-cyhalothrin, TCs derived in the USEPA Residential SOPs for activities conducted on gardens and trees, and turf were used.

Dislodgeable foliar residue (DFR) and turf transferrable residues (TTR) refer to the amount of residue that can be dislodged or transferred from a surface, such as the leaves of a plant or turf.

There were no adequate chemical-specific dislodgeable foliar residue (DFR) or turf transferable residue (TTR) studies submitted to the PMRA for the re-evaluation of lambda-cyhalothrin; therefore, the following defaults were used:

- For gardens and trees, a default peak value of 25% of the application rate with a dissipation rate of 10% per day was used for DFR;
- For turf, a default peak value of 1% of the application rate with a dissipation rate of 10% per day was used for TTR.

Postapplication residential exposure to lambda-cyhalothrin is generally expected to be short- to intermediate term (that is, from 1 day to several months) in duration.

The following lifestages and routes of exposure were assessed:

- Adults, youth, and children (6 to <11 years old) dermal exposure to residues produced by foliar applications in gardens and to trees
- Adult, youth, and children (1 to <2 years old) dermal exposure to residues produced by broadcast applications on turf, including golf courses
- Children (1 to <2 years old) incidental oral (hand-to-mouth) exposure to residues produced by broadcast applications to residential turf

Inhalation exposure to vapours was considered to be minimal due to the low vapour pressure of lambda-cyhalothrin and expected dilution in outdoor air. In addition, label directions specify that entry to treated areas must not occur until residues have dried, and therefore, inhalation of spray particles is not expected, since the spray droplets are expected to settle.

The calculated MOEs from dermal exposure were greater than the target MOE for all lifestages for all scenarios (see Appendix VII, Tables 2-3) and were not of concern.

For hand-to-mouth exposure, target MOEs were not met for turf application, and therefore there are risks of concern for children (see Appendix VII, Tables 6-8). As there were risks of concern identified for hand-to-mouth exposure, an object-to-mouth risk assessment was not conducted.

Since risks of concern were identified for hand-to-mouth exposures for children for residential turf application, application of lambda-cyhalothrin to residential turf (with the exception of golf courses) is proposed for cancellation. Application to non-residential turf is permitted. Proposed label directions will include definitions of residential and non-residential areas, with specific examples for each, as follows:

Residential areas are defined as any use site where the general public, including children, could be exposed during or after application. For outdoor areas, this includes homes, schools, parks, playing fields, cemeteries or any other areas where children could be present. Outdoor non-residential areas include right-of-way and around industrial buildings.

3.4.2.3 Residential Postapplication Cancer Risk Assessment

Postapplication activities presented lifetime cancer risks of concern for all indoor scenarios except crack and crevice. No lifetime cancer risks of concern were identified for gardens and trees, and golf courses. However, lifetime cancer risks were identified for residential turf application (excluding golf courses). The residential postapplication cancer risk assessment is outlined in Appendix IX, Tables 11-14.

3.4.3 Occupational Exposure and Risk Assessment

Workers can be exposed to lambda-cyhalothrin while mixing, loading or applying the pesticide, and when entering a treated site to conduct activities such as scouting and/or handling treated crops.

3.4.3.1 Handler Exposure and Risk Assessment

There are potential exposures to mixers, loaders and applicators. As per the supported uses, the following activities were assessed:

- Mixing/loading liquids
- Aerial liquid application to alfalfa, barley, brassica vegetables/cole crops (including broccoli, cavolo broccolo, Chinese broccoli (gai lan), Chinese mustard cabbage (gai choy), Chinese napa cabbage, Brussels sprouts, kohlrabi), buckwheat, canola, corn (including field, pop, sweet types, and crops grown for seed production), flax, grass mixtures, legume vegetables (including beans, chickpeas, fava beans, broad beans, lentils, peas, soybeans), mustard, oats, pearl millet, poplar and willow plantings, potatoes, proso millet, rice, rye, sorghum, summerfallow, sunflowers, teosinte, triticale, unimproved pasture, wheat, wild rice
- Aerosol (pressurized product) application to indoor/outdoor residential, industrial and commercial buildings/structures, and modes of transport (indoor/outdoor), pet kennels, livestock/poultry housing
- Airblast application to apples, cherries, nectarines, outdoor ornamentals, peaches, pears, plums, poplar and willow plantings, Saskatoon berries, shelterbelts (chokecherry)
- Groundboom liquid application to alfalfa, asparagus ferns, barley, brassica vegetables/cole crops (incl. broccoli, cavolo broccolo, Chinese broccoli (gai lan), Chinese mustard cabbage (gai choy), Chinese napa cabbage, Brussels sprouts, kohlrabi), buckwheat, canola, canola oilseed, carrots, celery, corn (incl. field, pop, sweet types, and crops grown for seed production), cucurbit vegetables (including chayote (fruit), Chinese waxgourd, citron melon, cucumber, edible gourd, gherkin, momordica spp., pumpkin, summer squash, winter squash, watermelon), flax, garlic (incl. greatheaded elephant), grass mixtures, legume vegetables (including beans, chickpeas, fava beans, broad beans, lentils, peas, soybeans), lettuce (head and leaf), mustard, oats, onion (including dry bulb,

leek, shallot, green), pearl millet, potatoes, proso millet, rice, rye, sorghum, Saskatoon berries, shelterbelts (chokecherry), strawberries, summerfallow, sunflowers, sweet potato, teosinte, timothy (grown for hay or seed), tobacco (cover crop treatment), tobacco (post-planting treatment), tobacco (soil treatment), tomatoes, triticale, turf (incl. sod, golf courses, home, industrial and commercial lawns), unimproved pasture, wheat, wild rice

- Mixing/loading/applying by manually-pressurized handwand and backpack to lettuce (greenhouse), Saskatoon berries, shelterbelts (chokecherry), tobacco seedlings (greenhouse), turf (including sod, golf courses, homes, industrial and commercial lawns)
- Mixing/loading/applying by mechanically-pressurized handgun to lettuce (greenhouse), shelterbelts (chokecherry), tobacco seedlings (greenhouse), turf (including sod, golf courses, homes, industrial and commercial lawns)
- Mixing/loading/applying by right-of-way (ROW) application to shelterbelts (chokecherry)
- Mixing/loading/applying by turf sprayer application to turf (including sod, golf courses, homes, industrial and commercial lawns)
- Dipper or applicator gun application to beef cattle and calves (all weights)
- Ear tag system (slow-release generator) for beef and non-lactating dairy cattle
- Mixing/loading/applying by structural manually-pressurized handwand application on or around residential/industrial/commercial structures, including indoor/outdoor band/spot and crack and crevice application

Based on the number of applications and the timing of application, workers applying lambda-cyhalothrin would generally have a short (<30 days) duration of exposure. Custom applicators may also have intermediate-term (for example, up to several months) exposure for those crops with multiple applications. Greenhouse applications can occur year-round, potentially resulting in long-term exposure scenarios.

Handler exposure was estimated based on the following personal protective equipment (PPE):

Baseline PPE:	Long sleeved shirt, long pants and chemical-resistant gloves (unless otherwise specified). For groundboom application, this scenario does not include gloves as the data quality was better for non-gloved scenarios than gloved scenarios.
Mid-level PPE:	Cotton coveralls over a long-sleeved shirt and long pants and chemical-resistant gloves.
Maximum PPE:	Chemical-resistant coveralls over a long-sleeved shirt and long pants and chemical-resistant gloves.
Engineering Controls:	Closed tractor cab for groundboom application with baseline or mid-level PPE. Closed liquid mix/load system with baseline or mid-level PPE.
Chemical-Resistant Headgear:	Chemical-resistant headgear that covers the neck (for example, Sou'Wester hat, rain hat).

Respirator:	A respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides, or a NIOSH approved canister approved for pesticides.

No chemical-specific studies were available to estimate handler exposure. Therefore, dermal and inhalation exposures were estimated using data from the *Pesticide Handlers Exposure Database* (PHED), *Version 1.1*, Agricultural Handlers Exposure Task Force (AHETF), and Outdoor Residential Exposure Assessment Task Force (ORETF). The PHED is a compilation of generic mixer/loader applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates based on formulation type, application equipment, mix/load systems and level of personal protective equipment (PPE). The open cab airblast scenario from AHETF and the professional turf sprayer application scenario from ORETF were used in the risk assessment. While there are limitations in the use of generic data, these exposure data represent the most reliable information currently available. In most cases, PHED and AHETF did not contain appropriate data sets to estimate exposure to workers wearing chemical resistant coveralls or a respirator. This was estimated by incorporating a 75% clothing protection factor for coveralls, a 90% protection factor for chemical resistant coveralls, and a 90% protection factor for a respirator (such as full and half-face air purifying and supplied air) into the unit exposure data.

Lambda-cyhalothrin is registered for dipper gun and ear tag applications (to cattle) for which no PHED scenarios exist. It was assumed that the exposure from mixing/loading and applying lambda-cyhalothrin by a manually-pressurized handwand would address the dipper gun method for livestock applications. For ear tag, it was assumed that dermal contact with the active ingredient is limited, and that inhalation exposure is also unlikely. For these reasons, a qualitative assessment was conducted for these scenarios.

For most agricultural food and non-food uses of lambda-cyhalothrin, target MOEs were met for handlers wearing baseline PPE, and do not require further mitigation. However, for some uses (for example, legumes, outdoor ornamentals), additional mitigation is required to reach target MOEs. Mitigation measures include engineering controls (closed cab for large area groundboom applications), respirator, chemical-resistant headgear for airblast application, and limits on the amount of product that can be applied in a day. For structural uses, target MOEs were met using baseline PPE.

Handler cancer risk estimates associated with applying, mixing and loading for all current label uses are not of concern when the above mitigation is used.

The occupational cancer and non-cancer risk assessment is summarized in Appendix X, Table 15.

3.4.3.2 Postapplication Worker Exposure, Cancer and Non-Cancer Risk Assessment

The occupational postapplication risk assessment considered exposures to workers who enter treated sites to conduct work-related activities. Work sites include agricultural areas (including greenhouses), outdoor non-agricultural areas such as golf courses, and buildings and other areas for structural pest control.

For structural applications, workers could enter treated areas in the following sites:

- Homes, schools and other residential areas
- Hotels and motels
- Nursing homes and hospitals
- Factories, laboratories, stores and warehouses
- Aircraft, buses, rail cars, ships and trucks
- Food/feed handling establishments such as grain mills, kitchens, meat packing plants, poultry and egg processing plants and restaurants
- Pet kennels
- Livestock housing, including poultry houses

Agricultural and Outdoor Non-Agricultural Areas (Non-Structural):

Workers could conduct agronomic activities involving residue contact with treated surfaces, such as foliage. Based on the lambda-cyhalothrin use pattern, there is potential for short-to intermediate-term (>1 day to several weeks) postapplication exposure for most scenarios. For greenhouse uses, there is potential for intermediate- to long-term (from several months to a year) postapplication exposure.

Potential exposure to postapplication workers was estimated using updated activity-specific transfer coefficients (TCs) and dislodgeable foliar residue (DFR) or turf transferrable residue (TTR) values. The DFR or TTR refers to the amount of residue that can be dislodged or transferred from a surface, such as leaves of a plant. The TC is a measure of the relationship between exposure and DFRs for individuals engaged in a specific activity, and is calculated from data generated in field exposure studies. The TCs are specific to a given crop and activity combination (for example, hand harvesting apples, scouting late season corn) and reflect standard agricultural work clothing worn by adult workers. Activity-specific TCs from the Agricultural Re-Entry Task Force (ARTF) were used. Postapplication exposure activities for agricultural crops include (but are not limited to): harvesting, pruning, scouting and thinning. For more information about estimating worker postapplication exposure, refer to PMRA's regulatory proposal PRO2014-02 *Updated Agricultural Transfer Coefficients for Assessing Occupational Postapplication Exposure to Pesticides*.

There were no adequate chemical-specific dislodgeable foliar residue (DFR) or turf transferable residue (TTR) studies submitted to the PMRA for the re-evaluation of lambda-cyhalothrin; therefore, the following defaults were used:

- For outdoor crops, trees and gardens, a default peak value of 25% of the application rate with a dissipation rate of 10% per day was used for DFR

- For turf, a default peak value of 1% of the application rate with a dissipation rate of 10% per day was used for TTR
- For greenhouse ornamentals, a default peak value of 25% of the application rate with a dissipation rate of 2.3% was used for DFR
- For all other greenhouse crops, a default peak value of 25% of the application rate with a dissipation rate of 0% was used for DFR

PMRA's Science Policy Note SPN2014-02, *Estimating Dislodgeable Foliar Residues and Turf Transferable Residues in Occupational and Residential Postapplication Assessments* presents further details on the derivation and use of these defaults for pesticide assessments.

For workers entering a treated site, restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before people can safely enter after application to perform tasks involving hand labour. An REI is the duration of time that must elapse in order for residues to decline to a level at which there are no risks of concern for postapplication worker activities (for example, in the case of lambda-cyhalothrin, performance of a specific activity that results in exposures above the target MOE of 300 or below the cancer threshold of 1×10^{-6}).

The PMRA is primarily concerned with the potential for dermal exposure to workers performing postapplication activities in crops treated with a foliar spray. Based on the vapour pressure of lambda-cyhalothrin, inhalation exposure is not likely to be of concern at the minimum REI of 12 hours.

Although there is potential dermal exposure to workers handling treated livestock following ear-tag or pour-on applications, the exposure associated with these activities is expected to be lower than exposure from activities for other uses on the label.

Calculated dermal MOEs for agricultural worker postapplication exposure to lambda-cyhalothrin in most commercial crops exceeded target MOEs and were below the cancer threshold, and therefore are not of concern. REIs were set at the standard minimum value of 12 hours for postapplication activities for these crops. The crops where risks of concern were identified (for example, broccoli, Brussels sprouts, cauliflower, onion, corn, and cut flowers) require longer REIs (up to 12 days). For non-agricultural areas, (for example, rights-of-way, turf in industrial areas), entry is permitted after residues have dried. The postapplication exposure and non-cancer risk assessment is summarized in Appendix X, Tables 16 and 17.

Structural Uses:

For postapplication occupational exposures of lambda-cyhalothrin, a separate assessment was not conducted. The assessment for postapplication exposure to adults in residential areas was considered to be representative for non-residential areas. This assumption is based on the duration and degree of contact with treated surfaces, which is assumed to be greater in residential areas.

As noted in Section 3.4.2.2, crack and crevice applications are permitted in non-residential areas, while band and spot application, and bedbug application, will be cancelled. Proposed label directions will include definitions of residential and non-residential areas, as well as the definition and specific use instructions for crack and crevice applications.

3.5 Aggregate Exposure and Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

3.5.1 Toxicology Endpoint Selection for Aggregate Risk Assessment

For the aggregate risk assessment of the general population (including pregnant women, infants and children) for any duration, the selected toxicological endpoints are clinical signs of neurotoxicity. For oral aggregate risk, the point of departure for lambda-cyhalothrin is the same as that identified for the acceptable daily intake, namely 0.1 mg/kg bw/day. For inhalation aggregate risk assessment, the point of departure for lambda-cyhalothrin is the same as that identified for the inhalation risk assessment (0.08 mg/kg bw/day). With regards to the dermal route, the point of departure for lambda-cyhalothrin is the same as that identified for the dermal risk assessment (10 mg/kg bw/day). The target MOE for all routes is 300.

Cancer Potency Factor:
See Section 3.4.1 above.

3.5.2 Non-Occupational and Dietary Aggregate Exposure and Risk Assessment

The aggregate assessment was based on exposures for uses that did not have any risk concerns. For lambda-cyhalothrin, these uses were exposure from drinking water and residential exposure from gardens and trees, and from turf in golf courses. The dermal exposure from use of lambda-cyhalothrin in gardens and trees, as well as golf courses (turf), is assumed to co-occur with background (chronic) dietary (drinking water) exposure for adults, youth (11<16 years old), and children (6<11 years old).

As noted in Appendix XI, tables 18-19, aggregate MOEs exceeded the target MOE for all scenarios and sub-population, and were not of concern. The aggregate lifetime cancer risks for all scenarios and sub-populations were also not of concern.

3.5.3 Human Biological Monitoring Data

Biological monitoring or biomonitoring is a method of assessing exposure to a pesticide by measuring the pesticide or its metabolites in biological media, such as urine or blood. Compared to ambient monitoring, biological monitoring has the advantage that it provides an integrated estimate of exposure through all relevant routes (respiratory, dermal and oral) and by all possible pathways (for example, food, drinking water and indoor uses) and reflects behavioural and physical sources of variability.

It differs from the standard approach for aggregate human health risk assessments, in which exposure models and algorithms are used to estimate route-specific exposures using measurements of pesticide concentrations in the environment or what is deposited on the skin, inhaled, and/or consumed for specific scenarios.

Human biomonitoring (HBM) data can be used to establish baseline levels of chemicals, to compare exposures, assess the effectiveness of exposure management strategies and to identify priorities. HBM data are considered to be refined since they are reflective of the 'real-life' use of chemicals and, in the case of population biomonitoring surveys, would represent aggregate risk for the general population. Therefore, HBM data may be used when evaluating aggregate exposure to a pesticide to support risk estimates generated using PMRA's standard approach for human health risk assessments.

HBM data from the Canadian Health Measures Survey (CHMS; cycles 1 & 2; 2007-2011) and the Maternal-Infant Research on Environmental Chemicals – Child Development (MIREC CD-plus; 2013-2014) were considered in the lambda-cyhalothrin re-evaluation.

The CHMS is an on-going, nationally representative health measures survey that has been conducted by Statistics Canada, in partnership with Health Canada and the Public Health Agency of Canada, since 2007. The cross-sectional survey collects information from Canadians such as physical measures (for example, height and weight) and general health (for example, blood pressure and fitness), as well as a biomonitoring component. It follows a similar study design to the United States National Health and Nutritional Examination Survey (NHANES) biomonitoring component. In Cycle 1 of the CHMS (2007-2009), blood and spot urine samples were collected from approximately 5,600 Canadians, 6-79 years old. In Cycle 2 (2009-2011), children as young as 3 years old were included. Pyrethroid metabolites were included in the suite of compounds measured.

The MIREC study was a national-level multi-year study that recruited approximately 2,000 women in the first trimester of pregnancy from 10 cities across Canada [Arbuckle *et al.*, 2013]. Women were followed over the course of their pregnancy to measure their exposure to environmental chemicals and examine potential health risks associated with these exposures. The Maternal-Infant Research on Environmental Chemicals-Child Development plus (MIREC-CD Plus) study, an off shoot of the MIREC study, recruited children between the ages of 15 months and 5 years of age from six of the most populous recruitment sites for the MIREC pregnancy cohort study. In addition to measuring their growth and neurodevelopment, blood and spot urine samples were collected from participating children. Approximately 200 urine samples from children under 3 years of age were analyzed. Data from the MIREC study were analysed at the request of PMRA under the Chemical Management Plan. Although the MIREC-CD Plus study aimed to collect urine from children that were 15 months to 3 years of age, there were no samples in the pyrethroid data set for children younger than 23 months.

Pyrethroid pesticides are rapidly metabolized and eliminated from the body through hydrolysis, oxidation, and conjugation. Following oral ingestion, inhalation or dermal exposure, pyrethroids are metabolized into carboxylic and phenoxybenzoic acids and excreted with urine. Pyrethroids and their metabolites can be measured in blood and urine, and are reflective of recent exposure to the parent compound or the metabolite in the environment.

For lambda-cyhalothrin, a chemical-specific metabolite is not excreted in the urine. Therefore, the common metabolite of 3-phenoxybenzoic acid (3-PBA) was used in the assessment. This is a conservative input (that is resulting in upperbound estimate of exposure), since 3-PBA is a common metabolite to other pyrethroids (for example, cypermethrin, permethrin, deltamethrin) and is also formed in the environment following pyrethroid application. It was assumed that all of the 3-PBA was metabolized from lambda-cyhalothrin. In addition, the 95th percentile values from CHMS and MIREC data were used to conduct the aggregate non-cancer risk assessment using the reverse dosimetry approach. For the cancer risk assessment, the arithmetic mean of 3-PBA was used from CHMS. These are also considered to be conservative values.

Reverse Dosimetry:
In addition to the CHMS and MIREC data, a human pharmacokinetic study was available for lambda-cyhalothrin (Marsh, Woollen and Wilks, 1994) and was used to determine the amount of 3-PBA metabolite excreted following administration of the parent compound, lambda-cyhalothrin. A urinary excretion fraction value of 25% was selected. The study was conducted in volunteers, followed informed consent procedures, and was approved by an independent ethics committee. As noted above, this approach is conservative, as 3-PBA is a metabolite common to 10 pyrethroids (for example, cypermethrin, permethrin, deltamethrin).

Equations for estimating daily urinary creatinine excretion were used to calculate daily exposure estimates. The CHMS and MIREC metabolite data have been normalized by each individual's body weight and extrapolated to a full day value using daily creatinine excretion values (determined for each individual based on their height and weight) using the equations from Mage *et al.* (2004).

The calculated aggregate MOEs based on human biological monitoring data were below the target MOE for the populations measured. This indicates that aggregate risk is of concern for these age groups, and supports the conclusions of the predictive assessment using the standard evaluation approach and assumptions (Appendix XI, Tables 20-21).

The available biomonitoing data are unlikely to capture incidental oral exposure in children (1 < 2 years of age), since children younger than 23 months were not included in the surveys.

These results support the conclusions of the risk assessment that risk mitigation is required based on the current registered uses of lambda-cyhalothrin, including food uses.

3.6 Cumulative Risk Assessment

The *Pest Control Products Act* requires the Agency to consider the cumulative effects of pest control products that have a common mechanism of toxicity. Lambda-cyhalothrin belongs to a group of insecticides commonly known as the pyrethroids. Pyrethroids and pyrethrins have a common mechanism of toxicity wherein they all possess the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. Upon completion of the re-evaluation of the individual chemicals in the pyrethroid group, it will be determined whether a cumulative effects assessment is necessary and if so, this will be performed with all relevant chemicals of the common mechanism group.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Lambda-cyhalothrin enters the terrestrial environment primarily when used as an insecticide against various insect pests on a variety of outdoor food and non-food crops, including apples, stone fruits, various berries, corn, cole crops, sunflowers, poplar and willow trees, and turf. Once in the terrestrial environment, lambda-cyhalothrin will breakdown through abiotic processes in alkaline conditions, and through biotic processes via aerobic degradation. In alkaline environments approaching pH 9, hydrolysis becomes an important route of transformation (DT50s between 1.3 and 17.8 days at pH 9, 20 to 25°C); however, the chemical becomes increasingly stable in pH environments of 7 or less. Under aerobic soil conditions, lambda-cyhalothrin is expected to be slightly persistent to persistent (aerobic soil DT50s of 7.2 to 9578 days). Two major transformation products are formed under aerobic conditions: (1RS)-cis-3-(ZE)-2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylic acid (referred to as compound Ia) and 1α(S*),3 α (Z)-(+/-)-cyano-[3-(4'-hydroxyphenoxy)phenylmethyl]-3-(2-chloro-3,3,3-trifluoro-1-prpenyl)-2,2-dimethylcyclopropanecarboxylate (hydroxylated lambda-cyhalothrin) (referred to as compound XV). Minor transformation products formed are 3-phenoxybenzoic acid (referred to as compound V), 3-phenoxybenzaldehyde (referred to as compound IV), and cyclopropanecarboxylic acid. Under anaerobic soil conditions, lambda-cyhalothrin is expected to be moderately persistent (DT_{50} 74 – 134 days). The major transformation product 3-phenoxybenzoic acid (compound V) can be formed under anaerobic conditions. Phototransformation in soil is not expected to be an important route of transformation. The proposed pathway of degradation results in transformation products eventually mineralizing further to carbon dioxide.

Lambda-cyhalothrin would be considered to be non-volatile under field conditions from the reported vapour pressure (2×10^{-4} mPa). The Henry's law constant (2×10^{-2} $Pa.m^3.mol^{-1}$), and 1/H value of 1.24×10^5, indicates that lambda-cyhalothrin is non-volatile from water and moist soil surfaces.

Lambda-cyhalothrin is practically immobile in soil due to strong adsorption onto soil particles and low solubility in water (0.005 mg/L). When taking into consideration the criteria of Cohen *et al.* (1984) and the groundwater ubiquity score (GUS) it was determined that lambda-cyhalothrin is likely a non-leacher. Soil column leaching and field leaching studies were not available; however, based on a K_{OC} of 70000-724000 lambda-cyhalothrin is not considered mobile in soil. In addition, there is no evidence of residue mobility under field conditions. Lambda-cyhalothrin residues, therefore, are not expected to leach into groundwater. Despite an extensive use pattern, lambda-cyhalothrin residues have seldom been detected in ground, treated drinking water, and ambient surface waters across Canada and the USA.

Lambda-cyhalothrin can enter the aquatic environment through spray drift and run-off from the application site. Hydrolysis is an important route of transformation under alkaline conditions but it is stable under neutral and acidic conditions. Phototransformation would contribute to the transformation of lambda-cyhalothrin within the photic zone of aquatic environments (DT_{50} = 8.5 to 30 days).

The major transformation products consistently detected in water were (1RS)-cis-3-(ZE)-2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylic acid (compound Ia) and 3-phenoxybenzoic acid (compound V), and 3-phenoxybenzaldehyde (compound IV).

In aquatic environments, lambda-cyhalothrin is expected to be non-persistent to moderately persistent (aerobic whole system DT_{50} = 12.6 to 60 days; anaerobic whole system DT_{50} = 62-93 days). Lambda-cyhalothrin dissipates rapidly from the water phase to the sediment, and the parent compound degrades by cleavage of the ester linkage. Two major transformation products were identified under aerobic conditions as (1RS)-cis-3-(ZE)-2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylic acid (compound Ia), and 1α(S*),3α (Z)-(+/-)-cyano-[3-(4'-hydroxyphenoxy)phenylmethyl]-3-(2-chloro-3,3,3-trifluoro-1-prpenyl)-2,2-dimethylcyclopropanecarboxylate (hydroxylated lambda-cyhalothrin) (compound XV). Subsequent minor degradation products are formed, which are eventually degraded to carbon dioxide.

The octanol/water partition coefficient (log K_{ow}) was reported to be 7 which indicates that lambda-cyhalothrin has a high potential for bioaccumulation in biota. Bioconcentration factor (BCF) values of 1500 to 2000 were determined for *Chironomus riparius* in a water only system, with 48 h aqueous BCF ranging from 1300 to 3400 in sediment/water systems. BCF values ranging from 3952 to 6691 were reported for fathead minnow, with an overall mean BCF of 4982 based on measured concentrations of lambda-cyhalothrin. A study with carp yielded a BCF of 2000 after 2 weeks of a 28 day exposure period, with 78% of residues being eliminated during the subsequent 28 day depuration period. This led to the conclusion that it will accumulate in fish during exposure but the majority is cleared from tissue within 30 days.

A summary of environmental fata data for lambda-cyhalothrin in the terrestrial and aquatic environment can be found in Tables 3 and 4 of Appendix XII, respectively.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative

application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to Terrestrial Organisms

A summary of terrestrial toxicity endpoints for lambda-cyhalothrin can be found in Table 5 of Appendix XII. For the environmental risk assessment, the toxicity endpoints from the most sensitive species within each taxonomic group were used as representative values for a wide range of organisms that can be potentially exposed to lambda-cyhalothrin through label use.

Earthworms
The risk quotients (RQs) for earthworms resulting from acute exposure to lambda-cyhalothrin were less than 1 and did not exceed the LOC at the screening level based on the EEC in soil from the highest cumulative application rate for agricultural uses (turf applications of 4x37.0 g a.i./ha with a 7 day interval). Lambda-cyhalothrin is not expected to pose a risk to earthworms under the registered use patterns.

Honey Bees
Honey bees are important pollinators and can be exposed to lambda-cyhalothrin from direct application or contact with treated plant material. The single highest application rate (37 g a.i./ha for turf), and a single application rate for multiple flowering crops that pollinators would be expected to frequent (28.43 g a.i./ha for group 5 and 6 crops) were used for the exposure estimates from foliar applications.

The risk quotients for acute contact and oral toxicity to honeybees exceeded the LOC (0.4) at both single application rates. As the screening assessment indicated that lambda-cyhalothrin could pose a risk to bees at these rates, a higher tiered risk assessment was conducted. For this, field and semi-field studies are considered, where available, and information is integrated to address potential short-term and long term effects on colony health. The assessment is qualitative in nature.

Several semi field and field studies were available for lambda-cyhalothrin and indicate that some effects (such as bee mortality, reduced flight intensity, behavioural abnormalities) may occur directly after application of lambda-cyhalothrin, but that these effects are short-lived and do not impact overall colony health. Due to short term effects, label statements directed towards minimizing spray drift, restricting application timing, and avoiding application on blooming plants are required to minimize potential exposure to pollinators.

Non-target Arthropods

At the screening level, risk to non-target arthropods was assessed using the maximum cumulative in-field and off-field EECs on plant surfaces, calculated from a direct spray on a field, and comparing these to the most sensitive endpoints for representative non-target arthropods. The in-field and off-field RQs exceeded the LOC of 2 for *Aphidius rhopalosiphi* (aphid parasitoid) and *Typhlodromus pyri* (predatory mite) at all levels except for *Aphidius rhopalosiphi* at off-field locations.

The risk to non-target arthropods was refined to reflect more realistic exposure by considering foliar interception. The screening level exposure estimates assume deposition to a 2-dimensional structure. Therefore, the values can be corrected to take into account the 3-dimensional structure of a crop canopy, where a certain fraction is intercepted by the crop plants (for in-field exposure) or the off-field vegetation (for off-field exposure). For the in-field EEC, crop-specific foliar interception factors (F_{int}) proposed by Linders *et al* (2000) are applied to the application rate. A factor of 0.9 was used for flowering/ripening sunflowers. For the off-field EEC, a vegetation distribution factor of 0.1 is applied to the application drift rate. This default value was estimated to be appropriate based on data presented at the ESCORT workshop (Candolfi *et al.* 2001).

The calculated refined RQs for non-target arthropods are shown in Table 6, Appendix XII. The refined in-field RQs still exceed the LOC of 2 for *A.rhopalosiphi* and *T.pyri* for both proposed applications on turf and sunflowers. The refined off field RQs still exceed the LOC for *T. pyri* and *A. rhopalosiphi* based on the proposed highest application rate on turf, and for *T.pyri* at the proposed highest application rate for sunflowers. Lambda-cyhalothrin is, therefore, expected to pose a risk at all application rates, and mitigative label statements are required for the protection of beneficial arthropods.

Terrestrial vascular plants

Limited data were available to assess the risk to terrestrial vascular plants. Given that the mode of action (insect nervous system toxin – in other words, disruption of action potential in neurons) does not apply to plants, adverse effects to terrestrial vascular plants are not anticipated. Lambda-cyhalothrin has been registered in Canada for many years for pest control on a variety of plant species at a wide range of application rates; no incidents have been reported in Canada indicating that lambda-cyhalothrin use causes adverse effects to terrestrial vascular plants. Six incident reports related to crop damage have been filed from the United States since 2014. Under American incident reports, it could not be confirmed that it was the use of lambda-cyhalothrin that caused the observed crop damage.

Based on the weight of evidence, lambda-cyhalothrin is not expected to pose a risk to terrestrial plants.

Terrestrial vertebrates

Birds and mammals would primarily be exposed to lambda-cyhalothrin through the ingestion of food items that have received spray from the product through direct application or from spray drift. The level of risk is assessed by considering the estimated daily exposure (EDE), which takes into account the expected amount of chemical on various food items immediately after the last application in conjunction with the food ingested per day, or the food ingestion rate (FIR), by different sized birds and mammals (small, medium, and large size classes).

At the screening level the most conservative exposure scenarios are used; the highest proposed cumulative application rates for all proposed application methods were considered, and only for those feeding groups that represent the highest potential exposure for each size class. For ground application, turf (highest seasonal application rate of 4 × 37 g a.i./ha), succulent pea crops/various crops (28.426 kg a.i./ha × 3 applications per season), crop subgroup 5A/various crops (for example, broccoli, cabbage brussel sprouts - 22.936 g a.i./ha × 3 applications per season), and strawberries (12.48 g a.i./ha × 3 applications per season) were used. In addition, the highest rates for airblast (various fruit crops – 12.688 g a.i./ha × 3 applications) and aerial (corn-19.08 g a.i./ha × 3 appplications) applications were considered at the screening level. Estimated drift deposition at 1 m downwind from the edge of the treated field may also be considered if required. Each cumulative application rate was based on a default half-life of 10 days for foliar dissipation between applications. This value is based on the foliar dissipation of a variety of active ingredients reported by Willis and McDowell (1987); with 93% of the foliar dissipation half-lives less than 10 days, this value is considered to be a reasonable conservative estimate of typical foliar half-lives. These six application scenarios represent the highest potential for exposure to birds and mammals, based on the highest cumulative application rates for each application method and by using the maximum residue concentrations expected on food items immediately after the last application.

Birds

At the screening level the LOC was exceeded for small and medium sized birds for the reproductive effects for turf and succulent pea crop applications, and for small birds only under crop subgroup 5A application. The screening level results indicate that lambda-cyhalothrin may have the potential to pose a risk to birds for certain size classes and feeding groups.

Given the conservative assumptions made at the screening level, an expanded assessment was conducted to further characterize the reproductive risk to birds. To further characterize the risk, the mean residue values were used for calculating EECs and EDEs instead of the maximum residue values used in the screening level risk assessment. The reproduction EDEs were calculated for each bird size and feeding group at the three application rates where RQs were exceeded at the screening level.

It is noted that the reproductive endpoint used in the risk assessment is based on an absence of effect; it was the highest concentration tested in the study, and no effects were observed at any concentration in the study. This makes the assessment conservative.

The results of the expanded screening level risk assessment for birds are presented in Tables 7 to 9, Appendix XII. Off-field RQs for birds did not exceed the LOC for any application scenarios. Therefore, the off-field risk to birds through the use of lambda-cyhalothrin is not expected to be of concern.

When considering mean residues on-field for all crops, RQs for reproduction marginally exceeded the LOC for small and medium-sized on turf only for insectivorous birds. Herbivores are a relevant feeding group to consider for turf environments since plant material would be the predominant food type available, and the RQs for all size classes of herbivores were below the LOC. Turf uses, particularly sod farms or golf courses, may not have a high prevalance of insects available for forage, and typically do not have a high abundance of birds foraging on insects in

these turf environments. Therefore, risks of concern to birds is unlikely under a turf application scenario. Since turf application represents the highest rate and the RQ only exceeds the LOC for the insectivore feeding guild; other application scenarios were also considered, including additional uses on crops where insect eating birds could more likely be present.

When considering the expanded assessment to other crops, the on-field RQs for reproduction for small (in succulent pea crop and crop subgroup 5A applications) and medium sized insectivorous birds (succulent pea crop application) marginally exceed the LOC for maximum residues only. Insect food sources would likely be present in these crop types; however, this risk would assume that birds are being exposed to residues on food items at levels equivalent to those present immediately after application, that these levels remain constant over time, and that birds would feed exclusively on a single food item (for example, small insects) within the treated area. In cases where risk quotients exceed the LOC, an additional analysis can be conducted to determine the amount of contaminated food, expressed as a percentage of the daily diet that must be consumed in order to reach the LOC (calculated as 1/RQ × 100). Given the conservative nature of this assessment, an acute and/or reproductive risk to birds on-field is considered unlikely because the LOC's were only slightly exceeded for insectivores and birds would need to consume an unrealistically large proportion of a single contaminated food item over an extended time period (75-96% of their diet on-field using maximum residues for use on peas and 93% of their diet on-field using maximum residues for use on crop subgroup 5A to reach the LOC.

Therefore, based on the low likelihood of insectivorous birds frequenting turf crops, and the unlikely situation where 100% of the food diet of insectivore birds in other crop areas would come from food containing maximum residue levels, and because the reproductive endpoint used in the assessment is not associated with observed effects, the overall risk to birds through the use of lambda cyhalotrhin is not expected to be of concern.

Mammals

At the screening level the LOC was exceeded for acute and reproductive effects for all sized mammals for turf, succulent pea crops, and crop subgroup 5A, and reproductive effects for all sized mammals and acute effects for medium sized mammals for strawberry, airblast, and aerial applications. At the screening level, lambda-cyhalothrin may have the potential to pose a risk to mammals for certain size classes and feeding guilds.

Given the conservative assumption made in the screening level, an expanded assessment was conducted to further characterize the risk to mammals. To further characterize the risk, the mean residue values were used for calculating EECs and EDEs instead of the maximum values used in the screening level risk assessment. The acute and reproduction EDEs were calculated for each size and feeding preference at the six application rates where RQs were exceeded at the screening level. The risk associated with the consumption of food items contaminated from spray drift off the treated field was assessed taking into consideration the spray drift quality of ASAE medium spray for ground applications (6%), fine spray for airblast (74% early; 59% late), and medium spray for aerial applications (23%) at 1 m downwind from the site of application.

The results of the expanded screening level risk assessment for wild mammals are presented in Tables 10 to 16, Appendix XII.

No off-field RQs for mammals exceeded the LOC for any application scenarios. Therefore, the off-field risk to mammals through the use of lambda-cyhalothrin is not expected to be of concern.

When considering wild mammals exposed to mean residue levels, potential acute and reproductive risk was observed for various feeding guilds for most mammal size classes under all application scenarios. Potential effects cannot be discounted since the residues on the food items within some of the food guilds where the LOC was exceeded are among the highest. For small and medium sized mammals in particular, their forage range is limited and much of their diet could be from food containing the residues.

Based on there being potential for risk under expanded scenarios, a label statement will be required to inform the user of the potential hazard to mammals.

4.2.2 Risks to Aquatic Organisms

A summary of aquatic toxicity data for lambda-cyhalothrin is presented in Table 17, Appendix XII.

Screening Level Assessment

The initial aquatic assessment is conservative, and primarily designed to identify the taxonomic groups which are not at risk and/or the use scenarios which do not pose an unacceptable risk. The initial conservative screening level EEC calculations for aquatic systems were based on a direct application to water depths of 15 and 80 cm following a single application at 5.04 g a.i./ha (cole crops, sunflower and tobacco), which is the lowest registered application rate in Canada. The 15 cm depth was chosen to represent a temporary body of water that could be inhabited by amphibians. The 80 cm depth was chosen to represent a typical permanent water body for applications of pest control products in agriculture. Where the LOC is not exceeded using EECs based on this rate, the RQs are re-calculated using the EEC(s) based on the highest registered outdoor broadcast application rate in Canada for turf (37 g a.i./ha × 4 applications with 7 day interval between applications), and using a freshwater aerobic biotransformation DT50 of 35.4 days to account for dissipation between applications.

Toxicity endpoints used for the aquatic risk assessment were drawn from sensitive test species under laboratory conditions for acute and chronic invertebrate studies, acute and chronic fish studies, and acute algae studies. No data were available for aquatic vascular plants. In the case of freshwater fish and aquatic invertebrates, multiple acute toxicity endpoints from various sensitive species were available (Table 17, Appendix XII) and were used to generate a species sensitivity distribution (SSD) based on normally distributed toxicity data. The hazardous concentration to 5% of the species (HC5) was then calculated from their respective SSD's. The HC5 values were used to calculate the risk quotients for these groups of taxa instead of the most sensitive species tested. In the case of freshwater fish, this single value was also used as a surrogate value when assessing risk for amphibians, as amphibian testing was not conducted.

At the screening assessment, the level of concern (LOC) is exceeded for all freshwater and estuarine/marine taxa with the exception of freshwater algae following a single application of 5.04 g a.i./ha. Since this is the lowest application rate registered in Canada, the RQs resulting from all the remaining registered uses will be higher. The LOC for freshwater algae following an application of 37 g a.i./ha × 4 on turf (the highest rate registered in Canada) was exceeded. A refined aquatic risk assessment, therefore, was conducted for all taxa.

Refined Risk Assessment for Aquatic Organisms

The screening level assessment is based on the conservative assumption that exposure is through direct overspray. Refinement options were utilised to better characterize risk to aquatic organisms by considering potential exposure due to spray drift and runoff separately.

Spray drift

The risk to aquatic organisms via spray drift downwind from the treated site was assessed for ground boom application (medium spray quality, 6% drift), airblast early season (fine spray quality, 74% drift) and late season application (fine spray quality, 59% drift), and aerial application (medium spray quality, 23% drift) at 1 m downwind from the site of application. The EECs are for the lowest rates for the given application method and timing. Where RQs do not exceed the LOC, these were recalculated using the EECs from the highest rate. Table 18 and 19, Appendix XII, summarizes the refined risk assessment for drift of lambda-cyhalothrin at lowest single application rate and highest rate for all application methods to aquatic organisms.

Using spray drift EECs derived from the lowest application rates, the LOC is exceeded for aquatic organisms and all application methods, except for freshwater fish and algae, and marine fish for ground boom. At the highest application rates for these latter three groups, the LOC was exceeded for algae exposed to early and late airblast, and freshwater and marine fish for all drift scenarios. Buffer zones will, therefore, be required to mitigate the risk to aquatic organisms.

Buffer zone distances are presented in Appendix XII. Buffer zones are determined using PMRA spray drift deposition models for field sprayer and airblast equipment and AGDISP v.8.21 software for fixed- and rotary wing aircraft. The maximum buffer zone distances are capped at 120 m for ground application and at 800 m for aerial application. These maximum distances are based on the limit of empirical drift deposit data generated for these methods of application. At the larger distances that are downwind from the point of application, the drift deposit is highly variable with only incremental decreases in spray deposit with distance. For extrapolation beyond these distances, there is, therefore, considerable uncertainty with predicted spray deposition. The spray drift models also do not take into consideration potential drift interception by adjacent vegetation, which can further reduce downwind deposition under field conditions.

Runoff

Aquatic organisms can be potentially exposed to lambda-cyhalothrin through runoff of water from treated areas into nearby water bodies. This was assessed through simulations using the PRZM/EXAMS models to predict EECs in receiving water bodies. For the Level 1 assessment, the modelled water body consists of a 1 ha wetland with an average depth of 0.8 m and a

drainage area of 10 ha. A seasonal water body was also used to assess the risk to amphibians, as a risk was identified at the screening level. This water body is essentially a scaled down version of the permanent water body noted above, but having a water depth of 0.15 m.

The maximum peak, 96 hour, and 21-day EEC's were used for the acute and chronic risk assessments, respectively, for the application scenarios to turf, soybean and tobacco across the country. The EECs for all durations are summarised in Table 20 in Appendix XII.

The results of the assessment are summarized in Table 21in Appendix XII. The acute LOCs are exceeded for freshwater invertebrates using the highest peak EECs for the application scenarios. The chronic LOCs are exceeded for freshwater invertebrates and fish and amphibians for some of the application scenarios. The acute and chronic LOC's for estuarine/marine taxa are exceeded for most of the application scenarios. Based on modelling results, aquatic organisms, therefore, may be at risk from lambda-cyhalothrin residues in runoff following applications for the different use-patterns across the country from both acute and chronic perspectives.

However, based on a search of monitoring data relevant for aquatic risk assessment purposes (Appendix XIII), data indicated that this chemical is seldom found in surface waters. In Canada lambda-cyhalothrin was detected in only 0.3% of surface water samples from water bodies such as lakes, rivers, and reservoirs, and 0.5% in the U.S. for similar water bodies. Higher proportions of detections (16%) were observed in U.S. surface waters such as ponds, ditches, and runoff, but no detections occurred in Canada for similar water bodies.

For aquatic risk assessment purposes, if the highest concentration of lambda-cyhalothrin detected in surface water from a sample in Quebec (0.17 µg/L , see Appendix XIII), is considered for an acute risk assessment, the level of concern is exceeded for aquatic invertebrates (RQ = 149) and fish (RQ = 1.5).

Due to the low detection frequency of lambda-cyhalothrin in water, it is difficult to estimate a long term exposure concentration based on available water monitoring data; as such, a chronic aquatic exposure assessment based on monitoring data cannot be conducted.

Based on the low frequency of lambda-cyhalothrin detection in Canadian surface waters, its low solubility in water, and environmental fate studies that demonstrate that lambda-cyhalothrin readily partitions into sediment, the potential for acute exposure of aquatic organisms to lambda-cyhalothrin in surface water is expected to be limited; chronic exposure of aquatic organisms to lambda-cyhalothrin in surface water is not expected. Standard label statements to reduce the potential for runoff into aquatic habitats will be required on the label for all lambda-cyhalothrin end-use products.

5.0 Value

Lambda-cyhalothrin has an extensive use pattern and contributes to pest management in Canada.

Lambda-cyhalothrin has one of the broadest registered agricultural use patterns for the synthetic pyrethroids and is one of the main alternatives to organophosphates and neonicotinoids. It is widely used to manage pests on berries, cereals, forages, oilseeds, pulses, tree fruits, vegetables, structural sites and livestock. Lambda-cyhalothrin is important as a rotational product for resistance management. In some cases it is the only pyrethroid registered or one of a limited number of active ingredients registered to control labelled pests. There are no alternative active ingredients to lambda-cyhalothrin for control of grasshoppers, tarnished plant bug or tent caterpillars on willow and poplar grown under short rotation intensive culture, or suppression of black vine weevil on strawberries.

Lambda-cyhalothrin is one of the pyrethroids used by pest control applicators in current pest management practices. The registrations of several carbamate and organophosphate insecticides that were used within structures have been discontinued (for example, bendiocarb, diazinon), or their use patterns have been amended, limiting their use to specific sites or to specific application methods (for example, dichlorvos, propoxur and chlorpyrifos), leading to the potential for limited resistance management options. Other pyrethroids currently registered for use in residential sites include cyfluthrin, permethrin, d-phenothrin, and tetramethrin.

Pesticide resistance is of major concern to the cattle industry. Lambda-cyhalothrin is one of a few insecticides registered for use on beef cattle and calves and non-lactating dairy cattle and it is important as a rotational product to help manage pests. Chemical control of face flies and horn flies and lice include pour-on veterinary drugs (eprinomectin and moxidectin), a limited number of organophosphates (dichlorvos, malathion and tetrachlovinphos), pyrethroids (cyfluthrin, cypermethrin and permethrin) and pyrethrins, with varying effectiveness due to resistance issues. To control ticks, permethrin is the only alternative insecticide registered for use on beef cattle and calves.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy, CEPA-toxic or equivalent, predominantly anthropogenic, persistent and bio-accumulative).

During the review process, lambda-cyhalothrin and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[2] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Lambda-cyhalothrin does not meet all Track 1 criteria, and is not considered a Track 1 substance. See Table 22 in Appendix XII for comparison with Track 1 criteria.
- Lambda-cyhalothrin does not form any transformation products that meet all Track 1 criteria.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[3]. The list is used as described in the PMRA Notice of Intent NOI2005-01[4] and is based on existing policies and regulations including: DIR99-03 and DIR2006-02[5] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

Technical grade lambda-cyhalothrin and associated end-use products do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

7.0 Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA. Information on the reporting of incidents can be found on the Pesticides and Pest Management portion of the Health Canada website. The incident report data was considered in the re-evaluation of lambda-cyhalothrin.

As of February 28, 2017, the PMRA had received 95 human and 65 domestic animal incidents involving lambda-cyhalothrin.

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2 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*.

3 Canada Gazette, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern and in the order amending this list in the Canada Gazette, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613, Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.

4 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act*.

5 DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

Most incidents were minor in nature. Skin effects, headaches and eye irritation were commonly reported symptoms in the human incident reports, and vomiting, loss of appetite and confusion were most commonly reported in the domestic animal incidents.

Generally, incidents occurred during the use of the product or upon re-entry of a previously treated area. Accidental contact during product use is mitigated with the use of personal protective equipment, as directed by the product label. Re-entry incidents involved residents, workers or pets who were exposed to an area that had been treated by a commercial applicator. The product reported most frequently in these incidents was Demand CS Insecticide (Reg. No. 27428). The product label contains precaution statements instructing the user to vacate the premises during the application of the product. Re-entry is permitted once surfaces are dry.

A Canadian human major incident was received that involved a toddler who had been in a hotel room shortly after it had been treated with a lambda-cyhalothrin product. The child experienced seizures and was hospitalised. There was sufficient evidence to conclude that the incident was possibly related to lamda-cyhalothrin. This incident further supports the, proposed mitigation (see section 3.4.2.2) to cancel all residential uses of lamda-cyhalothrin, including structures (such as hotels) where the general public, and children, may be exposed.

Environmental incident reports are obtained from two main sources, the Canadian pesticide incident reporting system (including both mandatory reporting from the registrant and voluntary reporting from the public and other government departments) and the USEPA Ecological Incident Information System (EIIS).

As of 28 February 2017, seven environmental incidents involving lambda-cyhalothrin were located in the PMRA database. One incident occurred after a fire broke out in a chemical storage warehouse and fish mortality was reported after dousing water used to put the fire out entered a stream. Several chemicals were involved in the incident report and it was difficult to distinguish the degree to which lambda-cyhalothrin may have contributed to the incident. The remaining incidents involved honeybee mortality following the alleged application of Matador 120EC or Endigo in neighbouring fields during bloom. Information was provided by multiple sources including the registrant, Ontario Ministry of the Environment and Climate Change, and the beekepers. There was sufficient evidence to conclude that the mortality observed in three of these reports was potentially related to the application of lambda-cyhalothrin. For the remaining reports it was considered unlikely that lambda-cyhalothrin contributed to the mortality.

The USEPA's Ecological Incident Information System was queried for lambda-cyhalothrin and cyhalothrin incidents that were available in the database as of August 26, 2016. There were 25 lambda-cyhalothrin and three cyhalothrin incident reports listed in the EIIS database. The reported organisms affected were bees (8 incidents), fish (9 incidents), aquatic invertebrates (2 incidents) and crop plants (6 incidents).

The databases in Canada and the United States contained incident reports with pollinator effects suspected to be related to the application of lambda-cyhalothrin on neighbouring fields. Lambda-cyhalothrin is highly toxic to pollinators, and as such, when pollinators are exposed to lambda-cyhalothrin, effects to pollinators are expected. As a result of the current re-evaluation, additional mitigation measures are proposed to protect pollinators when products containing lambda-cyhalothrin are used.

The USEPA EIIS database contained a number of incident reports with effects on aquatic organisms following spray application of products containing lambda-cyhalothrin. Most of the incidents occurred as a result of runoff or spray drift. A risk to non-target aquatic organisms was identified in the current risk assessment and additional mitigation measures are proposed to protect aquatic organisms by means of buffer zones and label statements.

The USEPA EIIS database contains six incident reports for effects on plants, two of which were identified as misuse situations and an additional incident in which it was determined that it was unlikely that lambda-cyhalothrin contributed to the reported effects. The three remaining incidents were defined as possibly being related to the application of lambda-cyhalothrin. Two of the cases reported occurred in 2003 and 2004 with the most recent one reported in 2013. In the 2013 case the information available states that there was a variety of chemicals applied at the same time including thinners, adjuvants and plant growth regulators. Sufficient information is not available from the incident reports to indicate that there is a concern surrounding risk to non-target plants from the application of lambda-cyhalothrin

8.0 Organisation for Economic Co-operation and Development Status of Lambda-cyhalothrin

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups member countries and provides a forum in which governments can work together to share experiences and seek solutions to common problems.

As part of the re-evaluation of an active ingredient, the PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries. In particular, decisions by an OECD member country to prohibit all uses of an active ingredient for health or environmental reasons are considered for relevance to the Canadian situation.

Lambda-cyhalothrin is currently acceptable for use in other OECD member countries, including Australia, the European Union and the United States. As of January 2017, no decisions by OECD member country to prohibit all uses of lambda-cyhalothrin for health or environmental reasons have been identified

9.0 Proposed Re-evaluation Decision

After a thorough re-evaluation of the insecticide lambda-cyhalothrin, Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing continued registration of certain uses of lambda-cyhalothrin and removal of other uses based on human health risks of concern that have been identified.

9.1 Proposed Regulatory Action Related to Human Health

Based on the evaluation of available scientific information, mitigation measures are proposed to further protect human health, including cancellation of all registered food and feed uses in Canada. In addition, all Canadian MRLs for lambda-cyhalothrin, including those specified for imported food commodities, are proposed to be revoked. Considering the potential impact on trade between Canada and other countries, the PMRA will consult with all interested stakeholders before making a final decision on MRL changes.

To mitigate potential risks of residential and bystander exposures, all indoor structural uses in residential areas are to be cancelled, and indoor structural applications in non-residential areas are to be limited to crack and crevice applications only. Turf application in residential areas is to be cancelled, except for on golf courses.

9.1.1 Proposed Mitigation Related to Toxicology

- Additional label statements are required (see Appendix XIV).

9.1.2 Proposed Mitigation Related to Dietary Exposure

- All uses of lambda-cyhalothrin on food and feed are proposed to be cancelled.
- Maximum residue limits (MRLs) for lambda-cyhalothrin, including those specified for imported food commodities, are proposed to be revoked.

Add to product labels with use on chokecherry shelterbelt:

- "Do not harvest treated chokecherries for food."

9.1.3 Proposed Mitigation Related to Occupational and Residential Exposure

Mitigation measures for potential occupational risks to workers in food and feed crops are not included here, since these uses are proposed for cancellation (see Section 9.1).

In residential areas, the following uses are proposed for cancellation:

- All turf applications except for golf courses.
- All indoor structural applications including crack and crevice applications.

Indoor structural applications in non-residential areas are limited to crack and crevice applications. Label directions must specify that the product can only be applied using low pressure sprayer equipment with a pin stream nozzle to direct sprays into cracks and crevices.

The definitions of residential and non-residential areas, with specific examples, are to be added to product labels, as well as the definition of crack and crevice.

Residential areas are defined as any use site where the general public, including children, could be exposed during or after application. For structural uses, in residential sites, this includes homes, schools, restaurants, public buildings or any other areas where the general public

including children may potentially be exposed. Non-residential areas include, but are not limited to: industrial/commercial indoor sites (for example, laboratories, warehouses, food granaries); modes of transport in areas where passengers are not present (for example, buses, railcars, trailers); and animal housing (for example, livestock and poultry, pet kennels).

For turf, outdoor non-residential areas include areas such as rights-of-way and around industrial buildings. Non-residential structural uses on the current lambda-cyhalothrin labels include (but are not limited to) office buildings, adult-only shelters, meat packing and food processing plants, warehouses, food granaries.

Crack and crevice is defined as an application of pesticides with the use of a pin stream nozzle, into cracks and crevices in which pests hide or through which they may enter a building. It does not permit the treatment of surfaces. Such openings commonly occur at expansion joints, between different elements of construction, and between equipment and floors. These openings may lead to voids such as hollow walls, equipment legs and bases, conduits, motor housings, or junction or switch boxes.

In addition, label directions will be added prohibiting all indoor structural applications as band, spot or for bedbug treatment.

For mixers, loaders and applicators, the following mitigation measures are proposed:

- Label directions must be added to specify that when handling 10 kg or more of the active ingredient per day, a closed cab is required for groundboom application.
- Label directions must be added to specify that when applying by mechanically-pressurized handgun, a daily maximum of 0.35 kg of active ingredient per day may be used per person and a respirator must be worn.
- The respirator must have a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides, or a NIOSH approved canister approved for pesticides.
- Label directions must be added to specify that when applying by open-cab airblast, a chemical-resistant hat must be worn.

A best practices label statement will be added to minimize drift to areas of human habitation or activity.

9.1.4 Residue Definition for Risk Assessment and Enforcement

Currently, the residue definition for lambda-cyhalothrin in Canada is lambda-cyhalothrin and its epimer. No change is proposed to this residue definition *per se* as a result of the re-evaluation. However, the residue definition for MRL enforcement will be revised to indicate residues are to be measured as the "Sum of lambda-cyhalothrin, a 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl (*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl (*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate, and its epimer, a 1:1 mixture of (*R*)-α-cyano-3-phenoxybenzyl (*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3-phenoxybenzyl (*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate expressed as lambda-cyhalothrin."

9.1.5 Maximum Residue Limits for Lambda-cyhalothrin in Food

Canadian MRLs for lambda-cyhalothrin are currently specified for a wide range of commodities. Residues in all other agricultural commodities, including those approved for treatment in Canada but without a specific MRL, are regulated under Subsection B.15.002(1) of the Food and Drugs Regulations, which requires that residues do not exceed 0.1 ppm. A complete list of MRLs specified in Canada can be found on the PMRA's MRL Database, an online query application that allows users to search for specified MRLs, regulated under the *Pest Control Products Act*, for pesticides or food commodities (http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php).The current MRLs for lambda-cyhalothrin are listed in Appendix VI of the Science Evaluation. All of these MRLs are proposed to be revoked as a result of the re-evaluation.

For supplemental MRL information regarding the international situation and trade implications, refer to Appendix VI.

9.2 Proposed Regulatory Action Related to the Environment

Potential risks of concern were identified for honey bees, non-target arthropods, mammals, freshwater and marine invertebrates, freshwater and marine fish, and freshwater algae. The following mitigation measures are proposed to further protect the environment:

- Environmental hazard statements for pollinators, beneficial arthropods, mammals, and aquatic organisms. On crops preferred by pollinator species, label statements will advise to avoid application during periods of bloom, or to apply during evening when bee foraging is minimal.
- Spray buffer zones between the point of application and non-target aquatic habitats.
- Label statements to reduce the potential for runoff.

10.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2016-04, *Management of Pesticides Re-evaluation Policy*, and DACO: tables can be found on the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra. PMRA documents are also

available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca

The federal Toxic Substances Management Policy is available through Environment Canada's website at www.ec.gc.ca/toxics.

List of Abbreviations

↑	increased
↓	decreased
µg	microgram(s)
µL	microlitre(s)
♀	females
♂	males
3-PBA	3-phenoxybenzoid acid
a.i.	active ingredient
abs	absolute
ADI	acceptable daily intake
ALP	alkaline phosphatase
ALT	alanine transaminase
APDM	aminopyrine demethylase
ARfD	acute reference dose
ARTF	Agricultural Re-entry Task Force
AST	aspartate aminotransferase
ATPD	area treated per day
AUC	area under the curve
BMDL	benchmark dose, lower confidence limit
BUN	blood urea nitrogen
bw	body weight
bwg	body weight gain
CAF	composite assessment factor
CDC	Centers for Disease Control and Prevention
CFIA	Canadian Food Inspection Agency
cm	centimetre(s)
cm^2	centimetres squared
C_{max}	maximum concentration
CMC	carboxymethylcellulose
DA	dermal absorption
DEEM-FCID	Dietary Exposure Evaluation Model - Food Commodity Intake Database
DFR	dislodgeable foliar residue
DMSO	dimethyl sulfoxide
DNA	deoxyribonucleic acid
DNT	developmental neurotoxicity
DT_{50}	half-life time
ECD	electron capture detector
EC50	Half maximal effective concentration
EEC	estimated environmental concentrations
ER (α, β)	estrogen receptor
ER	endoplasmic reticulum
ErC_{50}	EC_{50} in terms of reduction of growth rate
EyC_{50}	EC_{50} in terms of reduction of yield rate
et al.	and others
EUP	end use product

F_1	first generation
F_2	second generation
fc	food consumption
FOB	Functional Observational Battery
g	gram(s)
GC	gas chromatography
GD	gestation day
GLC	gas-liquid chromatography
GSH	glutathione
ha	hectare(s)
HC_5	hazardous concentration for five percent of the species
Hct	hematocrit
Hgb	hemoglobin
hr(s)	hour(s)
in vivo	performed or taking place in a living organism
iv	intravenous
kg	kilogram(s)
L	litre(s)
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
Log K_{OW}	octanol-water partition coefficient
LOAEL	lowest observed adverse effect level
M/L/A	mixer/loader/applicator
m	metre(s)
m^2	metres squared
MAS	maximum average score
MCH	mean cell hemoglobin
MCV	mean corpuscular volume
mg	milligram(s)
MIS	mean irritation score
mmHg	millimeters of mercury
MOE	margin of exposure
MRL	maximum residue limit
mRNA	messenger RNA
MSD	mass selective detector
n/a	not available
NCE	normochromatic erythrocytes
NCHS	National Center for Health Statistics
ND	not determined
NHANES	National Health and Nutrition Examination Survey
NOAEL	no observed adverse effect level
PCE	polychromatic erythrocytes
PCPA	*Pest Control Products Act*
PCT	percent crop treated
PDP	Pesticide Data Program
PEG	polyethylene glycol
per se	in itself

pH	potential of hydrogen
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
PMRA $DT_{50}/90/t_R$	Representative half-life
PND	post-natal day
PPE	personal protective pquipment
ppm	parts per million
PRZM-GW	Pesticide Root Zone Model Groundwater
q_1^*	cancer potentency factor
RBC	red blood cell
REI	restricted-entry interval
rel	relative
RfD	reference dose
ROW	right-of-way
RQ	risk quotient
SER	smooth endoplasmic reticulum
SOP	standard operating procedure
SWCC	Surface Water Concentration Calculator
$T_{1/2}$	half-life
T3	triiodothyronine
T4	thyroxine
TC	transfer co-efficient
TFP acid	3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropane carboxylic acid
TSH	thyroid stimulating hormone
TTR	turf transferable residue
USEPA	United States Environmental Protection Agency
USC	use site category
USDA	United States Department of Agriculture
WBC	white blood cell
wc	water consumption
wk	week
wt	weight
WWEIA	What We Eat in America

Appendix I Registered Lambda-cyhalothrin Products as of January 2017, Excluding Discontinued Products or Products with a Submission for Discontinuation

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
24984	Commercial	Syngenta Canada Inc.	Matador 120ec Insecticide	Emulsifiable concentrate or emulsion	Lambda-cyhalothrin 120 g/L
26646	Commercial	Intervet Canada Corp.	Saber Insecticide Ear Tag	Slow release generator	Lambda-cyhalothrin 10%
26837	Commercial	Syngenta Canada Inc.	Warrior Insecticide	Microcapsule suspension	Lambda-cyhalothrin 122 g/L
27428	Commercial	Syngenta Canada Inc.	Demand CS Insecticide	Microcapsule suspension	Lambda-cyhalothrin 100 g/L
27829	Commercial	Intervet Canada Corp.	Saber Pour-On Insecticide	Solution	Lambda-cyhalothrin 1.0%
27954	Commercial	Intervet Canada Corp.	Saber ER Premise Insecticide	Microcapsule suspension	Lambda-cyhalothrin 100 g/L
28485	Commercial	BASF Canada Inc.	Prescription Treatment Brand 221L Residual Insecticide Formula 2	Pressurized product	Lambda-cyhalothrin 0.05%
28499	Commercial	Syngenta Canada Inc.	Scimitar CS Insecticide	Microcapsule suspension	Lambda-cyhalothrin 100 g/L
28946	Commercial	Syngenta Canada Inc.	Lambda-Cyhalothrin CS Insecticide	Microcapsule suspension	Lambda-cyhalothrin 100 g/L
29052	Commercial	Adama Agricultural Solutions Canada Ltd.	Silencer 120 EC Emulsifiable Concentrate Insecticide	Emulsifiable concentrate or emulsion	Lambda-cyhalothrin 120 g/L
30325	Commercial	Syngenta Canada Inc.	Voliam Xpress Insecticide	Suspension	Lambda-cyhalothrin 50 g/L Chlorantraniliprole 100 g/L
30404	Commercial	Syngenta Canada Inc.	Endigo Insecticide	Suspension	Lambda-cyhalothrin 106 g/L Thiamethoxam 141 g/L
31300	Commercial	Syngenta Canada Inc.	Masterline Lambdacy Insecticide	Microcapsule suspension	Lambda-cyhalothrin 100 g/L
32243	Manufacturing concentrate	Nufarm Agriculture Inc.	NUP-14001 MUP	Solution	Lambda-cyhalothrin 3.84% Imidacloprid 19.19%

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
24567	Technical	Syngenta Canada Inc.	Lambda-Cyhalothrin Technical Insecticide	Liquid	Lambda-cyhalothrin 89%
29026	Technical	Adama Agricultural Solutions Canada Ltd.	Lambda-CY Technical Insecticide	Powder	Lambda-cyhalothrin 97.1%
30818	Technical	Syngenta Canada Inc.	Lambda-Cyhalothrin Technical 2 Insecticide	Solid	Lambda-cyhalothrin 98%
31604	Technical	Nufarm Agriculture Inc.	Nufarm Lambda-Cyhalothrin Technical	Solid	Lambda-cyhalothrin 97.0%
31668	Technical	United Phosphorus Inc.	UPI Lambda-Cyhalothrin Technical Insecticide	Solid	Lambda-cyhalothrin 95.3%
31859	Technical	Sharda Cropchem Limited	Sharda Lambda-Cyhalothrin Technical Insecticide	Solid	Lambda-cyhalothrin 95.27%
32427	Commercial	Adama Agricultural Solutions Canada Ltd.	Silencer 120 EC Low VOC	Emulsifiable concentrate or emulsion	Lambda-cyhalothrin 120 g/L

Appendix II Registered Commercial-Class Uses of Lambda-cyhalothrin in Canada as of January 2017, Excluding Uses of Discontinued Products or Products with a Submission for Discontinuation.

Site(s)	Pest(s)	Formulation Type[1]	Application Methods and Equipment	Application rate (a.i./ha)[2]		Maximum Number of Applications per year[2]	Minimum Interval Between Applications (days)[2]
				Maximum Single	Maximum Cumulative		
Use-site Category 5: Greenhouse Food Crops							
Greenhouse lettuce	Cabbage looper	EC	Ground equipment - foliar	9.96 g /ha	(19.92 g / ha)	2	[7]
		SU		10.13 g /ha	(20.26 g / ha)		7
Greenhouse tobacco seedlings,	Darksided cutworm, white cutworm	EC	Ground equipment - foliar	0.001 g /M^2 (10 g /ha)	(0.003 g /M^2) (30 g / ha)	[3]	Not stated
		SU		0.001 g /M^2 (10 g /ha)	(0.001 g /M^2) (10 g /ha)	[1]	Not applicable
Use-site Category 7: Terrestrial Non-food and Non-feed Seed and Fibre Crops							
Poplar, willow, including SRIC	Grasshoppers	EC	Ground: Airblast Sprayer Aerial	Ground: 9.96 g /ha Aerial: 9.96 g /ha	(Ground: 29.88 g /ha) (Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	7
		SU	Ground: Airblast Sprayer	10.13 g /ha	(30.39 g ha)	3	
	Potato leaf hopper, tarnished plant bug	EC	Ground: Airblast Sprayer Aerial	Ground: 9.96 g /ha Aerial: 9.96 g /ha	(Ground: 29.88 g /ha) (Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	
		SU	Ground: Airblast Sprayer	10.13 g /ha	(30.39 g /ha)	3	
	Prairie tent caterpillar, ugly nest caterpillar	EC	Ground: Airblast Sprayer	6.96 g /ha	(6.96 g /ha)	1	Not applicable
		SU		7.1 g /ha	(7. 1 g /ha)	1	
Use-site Category 8: Animals for Food Production							
Beef and non-lactating dairy cattle	Face flies, horn flies	Slow release generator	Ear tag	[161.5 mg /animal/ year]	(161.5 mg /animal/ year)	[1]	Not applicable
Beef cattle and calves (less than 275 kg)	Biting and sucking lice, horn flies, rocky mountain wood tick	SN	Pour on	0.097 g /animal/ year	(0.388 g /animal/ year)	4	21
Beef cattle and calves (more than 275 kg)				0.146 g /animal/ year	(0.584 g /animal/ year)		
Use-site Category 13: Terrestrial Feed Crops							
Timothy (grown for hay or seed)	Grasshoppers	EC	Ground equipment - foliar	9.96 g /ha	(29.88 g /ha)	3	7
		SU		10.13 g /ha	(30.39 g /ha)		

Site(s)	Pest(s)	Formulation Type[1]	Application Methods and Equipment	Application rate (a.i./ha)[2]		Maximum Number of Applications per year[2]	Minimum Interval Between Applications (days)[2]
				Maximum Single	Maximum Cumulative		
Alfalfa	Alfalfa weevil, lygus bug, tarnished plant bug, pea aphid, potato leafhopper	EC	Ground: boom Aerial: aircraft	9.96 g a.i./ha	(39.84 g /ha)	Ground: [4] Aerial: 1	[7]
		SU	Ground equipment - foliar	10.13 g /ha	(30.39 g /ha)	3	7
Alfalfa, summer-fallow, unimproved pasture	Grasshoppers	EC	Ground: boom Aerial	Ground: 9.96 g /ha Aerial: 9.96 g /ha	(Ground: 29.88 g /ha) (Aerial: 9.96 g /ha)	Ground: 3 Aerial: 1	
		SU	Ground equipment - foliar	10.13 g /ha	(30.39 g /ha)	3	
Use-site Category 14: Terrestrial Food Crops							
Sweet potato	Potato flea beetle, tuber flea beetle, potato leafhopper	EC	Ground: field sprayer	9.96 g /ha	(29.88 g /ha)	3	7
		SU		10.13 g /ha	(30.39 g /ha)		
Crop Group 3 Bulb Vegetables	Onion thrips, leek moth	SU	Ground: Field sprayer	22.94 g /ha	(68.82 g /ha)		
		EC		22.56 g /ha	(67.68 g /ha)		
Head lettuce	Cabbage looper, tarnished plant bug, darksided and white cutworms	EC	Ground: Field sprayer	9.96 g /ha	(29.88 g /ha)		
		SU		10.13 g /ha	(30.39 g /ha)		
Leaf lettuce	Tarnished plant bug	EC	Ground: Field sprayer	9.96 g /ha	(29.88 g /ha)		
		SU		10.13 g /ha	(30.39 g /ha)		
Crop Group 5A Head and Stem Brassica Subgroup	Onion thrips, black cutworm, armyworm, fall armyworm, beet armyworm, corn earworm, *Liriomyza* leafminers	SU	Ground: Field sprayer	25 g /ha	(75 g /ha)		
	Onion thrips	EC		22.56 g /ha	(67.68 g /ha)		
		SU		22.94 g /ha	(68.82 g /ha)		
Broccoli, Brussels sprouts, cabbage, cauliflower	Crucifer flea beetle, diamondback moth (larvae), imported cabbageworm	SU	Ground: Field sprayer	5.12 g /ha	(15.36 g /ha)		
		EC		5.04 g /ha	(15.12 g /ha)		
	Swede midge, cabbage looper	EC		9.96 g /ha	(29.88 g /ha)		
		SU		10.13 g /ha	(30.39 g /ha)		

Site(s)	Pest(s)	Formulation Type[1]	Application Methods and Equipment	Application rate (a.i./ha)[2]		Maximum Number of Applications per year[2]	Minimum Interval Between Applications (days)[2]
				Maximum Single	Maximum Cumulative		
Beans, succulent and dry edible	Bean leaf beetle	EC	Ground: field sprayer Aerial	Ground: 27.96 g /ha Aerial: 9.96 g /ha	(Ground: 83.88 g /ha) (Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	Ground: 7 Aerial: 4
		SU	Ground: Field sprayer	28.43 g /ha	(85.29 g /ha)	3	4
	Cutworms, corn borer, potato leaf hopper, lygus bugs	EC	Ground: field sprayer Aerial	Ground and aerial: 9.96 g /ha	(Ground: 29.88 g/ha) (Aerial: 19.92 g/ha)	Ground: 3 Aerial: 2	
		SU	Ground: Field sprayer	10.13 g /ha	(30.39 g/ha)	3	
	Soybean aphid, pea aphid, bean aphid	EC	Ground: field sprayer Aerial	Ground: 27.96 g /ha Aerial: 9.96 g /ha	(Ground: 83.88 g /ha) (Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	7
	Western bean cutworm			Ground: 22.44 g /ha Aerial: 9.96 g /ha	(Ground: 67.32 g /ha) (Aerial: 19.92 g /ha)		4
Chickpeas	Bean leaf beetle	SU	Ground: Field sprayer	28.5 g /ha	(85.5 g /ha)	3	
	Bean leaf beetle, grasshoppers, potato leafhopper	EC	Aerial	Aerial: 9.96 g /ha	(19.96 g/ha)	Aerial: 2	
	Bean leaf beetle, Western bean cutworm	EC	Ground: field sprayer Aerial	Ground: 22.44 g /ha Aerial: 9.96 g /ha	(Ground: 67.32 g /ha Aerial: 19.92 g /ha	Ground: 3 Aerial: 2	
	Cutworms		Ground: field sprayer Aerial	Ground and aerial: 9.96 g /ha	(Ground: 29.88 g /ha) (Aerial: 19.92 g /ha)		
	Grasshoppers, potato leafhopper		Ground: field sprayer	Ground: 9.96 g /ha	(Ground: 29.88 g /ha)	3	
	Grasshoppers, potato leafhopper, cutworms	EC	Ground: field sprayer Aerial	Ground and aerial: 9.96 g /ha	(Ground: 29.88 g /ha) (Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	
		SU	Ground: Field sprayer	10.13 g /ha	(30.39 g /ha)	3	
	Soybean aphid, pea aphid, bean aphid	EC	Ground: field sprayer Aerial	Ground: 27.96 g /ha Aerial: 9.96 g /ha	(Ground: 83.88 g /ha) (Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	7

Site(s)	Pest(s)	Formulation Type[1]	Application Methods and Equipment	Application rate (a.i./ha)[2]		Maximum Number of Applications per year[2]	Minimum Interval Between Applications (days)[2]
				Maximum Single	Maximum Cumulative		
Favabeans (broad beans)	Bean leaf beetle	EC	Ground: field sprayer Aerial	Ground: 27.96 g /ha Aerial: 9.96 g /ha	(Ground: 83.88 g /ha) (Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	4
		SU	Ground: Field sprayer	28.43 g /ha	(85.29 g /ha)	3	
	Lygus bugs, potato leafhopper, pea aphid	SU	Ground: Field sprayer	10.13 g /ha	(30.39 g /ha)		
	Potato leafhopper, lygus bugs	EC	Ground: field sprayer Aerial	Ground and aerial:9.96 g /ha	(Ground: 29.88 g /ha) (Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	
	Soybean aphid, pea aphid, bean aphid	EC	Ground: field sprayer Aerial	Ground: 27.96 g /ha Aerial: 9.96 g a.i. /ha	(Ground: 83.88 g /ha) (Aerial: 19.92 g /ha)		7
	Western bean cutworm	EC	Ground: field sprayer Aerial	Ground: 22.44 g /ha Aerial: 9.96 g /ha	(Ground: 67.32 g /ha) (Aerial: 19.92 g /ha)		4
Beans, succulent and dry edible	Corn borer	EC	Ground: field sprayer Aerial	Ground and aerial:9.96 g /ha	(Ground: 29.88 g /ha) (Aerial: 19.92 g /ha)		
Beans, succulent and dry edible, peas, succulent, fava beans (broad beans), chickpeas, lentils	Potato leafhopper	EC	Ground: field sprayer Aerial	Ground and aerial:9.96 g /ha	(Ground: 29.88 g /ha) (Aerial: 19.92 g /ha)		
Lentils	Grasshoppers, lygus bugs, potato leafhopper, cutworms	EC	Ground: field sprayer Aerial	Ground and aerial:9.96 g /ha	(Ground: 29.88 g /ha) (Aerial: 19.92 g /ha)		
	Pea aphid, grasshoppers, lygus bugs, potato leafhopper, cutworms	SU	Ground: field sprayer	10.13 g /ha	(30.39 g /ha)	3	
	Soybean aphid, pea aphid, bean aphid	EC	Ground: field sprayer Aerial	Ground: 27.96 g /ha Aerial: 9.96 g /ha	(Ground: 83.88 g /ha) (Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	7
	Western bean cutworm		Ground: field sprayer Aerial	Ground: 22.44 g /ha Aerial: 9.96 g /ha	(Ground: 67.32 g /ha) (Aerial: 19.92 g /ha)		4

Site(s)	Pest(s)	Formulation Type[1]	Application Methods and Equipment	Application rate (a.i./ha)[2]		Maximum Number of Applications per year[2]	Minimum Interval Between Applications (days)[2]
				Maximum Single	Maximum Cumulative		
Peas, succulent: pea (Pisum spp.), pigeon pea	Bean leaf beetle	SU	Ground: Field sprayer	28.43 g /ha	(85.29 g /ha)	3	4
		EC	Ground: field sprayer Aerial	Ground: 27.96 g /ha Aerial: 9.96 g /ha	(Ground: 83.88 g /ha) (Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	
	Cutworms, potato leafhopper	EC		Ground and aerial:9.96 g /ha	(Ground: 29.88 g /ha) (Aerial: 19.92 g /ha)		
	Soybean aphid, pea aphid, bean aphid	EC		Ground: 27.96 g /ha Aerial: 9.96 g /ha	(Ground: 83.88 g /ha) (Aerial: 19.92 g /ha)		7
	Western bean cutworm	EC		Ground: 22.44 g /ha Aerial: 9.96 g /ha	(Ground: 67.32 g /ha) (Aerial: 19.92 g /ha)		4
	Cutworm, pea aphid, potato leafhopper	SU	Ground: Field sprayer	10.13 g /ha	(30.39 g /ha)	3	
Crop Group 8-09 Fruiting Vegetables	Armyworm, fall armyworm, beet armyworm, variegated cutworm, tobacco hornworm, tomato hornworm, tomato fruitworm, corn earworm, European corn borer, cabbage looper, black cutworm, potato Psyllid	SU	Ground: Field sprayer	25 g /ha	(50 g /ha)	2	7

Site(s)	Pest(s)	Formulation Type[1]	Application Methods and Equipment	Application rate (a.i./ha)[2]		Maximum Number of Applications per year[2]	Minimum Interval Between Applications (days)[2]
				Maximum Single	Maximum Cumulative		
Tomatoes	Colorado potato beetle	EC	Ground: Field sprayer	15 g /ha	(30 g /ha)	2	7
		SU		15.25 g /ha	(30.5 g /ha)		
	Cutworms, potato flea beetle, potato leafhopper, tarnished plant bug	EC		9.96 g /ha	(29.88 g /ha)	3	
		SU		10.13 g /ha	(30.39 g /ha)		
Crop Group 9 Cucurbit Vegetables	Striped cucumber beetle, squash bug	EC	Ground: Field sprayer	27.96 g /ha	(83.88 g /ha)		
		SU		28.43 g /ha	(85.29 g /ha)		
	Striped cucumber beetle, squash bug, cabbage looper, black cutworm, armyworm, fall armyworm, corn earworm, leafminers	SU		25 g /ha	(75 g /ha)		
Pears	Codling moth, pear Psylla (adults & nymphs)	EC	Ground: Airblast Sprayer	9.96 g /ha	(9.96 g /ha)	1	Not applicable
		SU		10.13 g /ha	(10.13 g /ha)		
Cherries	Cherry maggot, plum curculio	EC		12.48 g /ha	(37.44 g /ha)	3	7
		SU		12.69 g /ha	(38.07 g /ha)		
Nectarines, peaches	Green peach aphid, oriental fruit moth, tarnished plant bug	EC		12.48 g /ha	(37.44 g /ha)		
		SU		12.69 g /ha	(38.07 g /ha)		
Plums	Plum curculio, mealy plum aphid	EC		12.48 g /ha	(37.44 g /ha)		
		SU		12.69 g /ha	(38.07 g /ha)		
Saskatoon berries	Saskatoon bud moth	EC	Ground: Field or air blast sprayer	12.48 g /ha	(24.96 g /ha)	2	10
		SU		12.69 g /ha	(25.38 g /ha)		

Site(s)	Pest(s)	Formulation Type[1]	Application Methods and Equipment	Application rate (a.i./ha)[2]		Maximum Number of Applications per year[2]	Minimum Interval Between Applications (days)[2]
				Maximum Single	Maximum Cumulative		
Strawberries	Bud (clipper) weevil, meadow spittle bug, tarnished plant bug, black vine weevil adults (suppression only)	EC	Ground: Field sprayer	12.48 g /ha	(37.44 g /ha)	3	7
		SU		12.69 g /ha	(38.07 g /ha)		
Crop Group 14-11 Tree Nuts (excluding ginkgo, monkey puzzle nut and pine nuts)	Oblique-banded leaf roller	SU	Ground: airblast sprayer	10.13 g /ha	(40.52 g /ha)	4	
		EC		9.96 g /ha	(39.84 g /ha)		
	Aphids	SU		12.69 g /ha	(38.07 g /ha)	3	
		EC		12.48 g /ha	(37.44 g /ha)		
Walnut, butternut, heartnut	Codling moth	SU	Ground: Airblast Sprayer	10.13 g /ha	(40.52 g /ha)	4	
		EC		9.96 g /ha	(39.84 g /ha)		
	Butternut curculio, walnut husk fly	SU		12.69 g /ha	(38.07 g /ha)	3	
		EC		12.48 g /ha	(37.44 g /ha)		
Celery	Tarnished plant bug	EC	Ground: field sprayer	9.96 g /ha	(29.88 g /ha)		
		SU		10.13 g /ha	(30.39 g /ha)		
Ferns of asparagus	European asparagus aphids	EC	Ground: field sprayer	9.96 g /ha	(29.88 g /ha)		
		SU		10.13 g /ha	(30.39 g /ha)		
Tobacco	Darksided cutworm, white cutworm	EC	Ground: field sprayer	Cover crop: 5.04 g /ha Soil or Post planting: 9.96 g /ha	(Cover crop: 5.04 g /ha Soil or Post planting: 9.96 g /ha)	1	Not applicable
		SU		Cover crop: 5.12 g /ha Soil or Post planting: 10.13 g /ha	(Cover crop: 5.12 g /ha Soil or Post planting: 10.13 g /ha)		
Use-Site Category 16: Non-agricultural, Industrial and Residential Pest Management for Non-Food Sites							
Chokecherry, shelterbelts	Prairie tent caterpillar, ugly nest caterpillar, fruit tree leafroller	SU	Ground: field sprayer	7. 1 g /ha	(7. 1 g /ha)	1	Not applicable
		EC		6.96 g /ha	(6.96 g /ha)		
Use-Site Category 20: Structures							
Residential, commercial, industrial, institutional and agricultural structures	Ants	Pressurized Product	Handheld equipment	0.3 g /can	Cannot be calculated from label	4	21

Site(s)	Pest(s)	Formulation Type[1]	Application Methods and Equipment	Application rate (a.i./ha)[2]		Maximum Number of Applications per year[2]	Minimum Interval Between Applications (days)[2]
				Maximum Single	Maximum Cumulative		
Residential, commercial, industrial, institutional and agricultural structures	Bees, Wasps And Yellowjackets	Pressurized Product	Handheld equipment	0.3 g/ can	Cannot be calculated from label	Not stated on label	Not stated on label
Residential, commercial, industrial, institutional and agricultural structures	Cockroaches, Spiders, Earwigs, Crickets, Sowbugs, Millipedes, Centipedes, Ticks, Booklice, Silverfish, Bedbugs, Ants, Flour Beetles, Grain Beetles	Pressurized Product	Perimeter treatment: Handheld equipment	0.3 g/ can		Not stated on label	21
Residential, commercial, industrial, institutional and agricultural structures (indoors only) Various transport vehicles.	Ants, Cockroaches, Crickets, Firebrats, Bedbugs	SU	Handheld or power operated application equipment as a coarse spray for crack and crevice treatments. Equipment capable of delivering a pin-stream spray in Food Handling Establishments.	0.016 g / M^2	(0.064 g / M^2)	4	21
Residential, commercial, industrial, institutional and agricultural structures (indoors only) Various transport vehicles.	Cockroaches, Spiders, Earwigs, Crickets, Sowbugs, Millipedes, Centipedes, Ticks, Booklice, Silverfish, Bedbugs, Ants, Hibernating Stages Of Flies (House, Stable, And Cluster), Flour Beetles, Grain Beetles, Indian Meal Moths	Pressurized Product	Band spot: Crack and Crevice. Handheld equipment	0.3 g/ can	Cannot be calculated from label	4	21
Residential, commercial, industrial, institutional and agricultural structures.	Ants, Centipedes, Crickets, Millipedes, Sowbugs, Cluster Flies	SU	Hand held or power operated application equipment as a coarse spray.	0.016 g / M^2	(0.064 g / M^2)	4	21

Site(s)	Pest(s)	Formulation Type[1]	Application Methods and Equipment	Application rate (a.i./ha)[2]		Maximum Number of Applications per year[2]	Minimum Interval Between Applications (days)[2]
				Maximum Single	Maximum Cumulative		
In-ground service boxes	Ants, Centipedes, Clover Mites, Cockroaches, Crickets, Earwigs, Fire Ants, Millipedes, Scorpions, Silverfish, Sowbugs, Spiders, Springtails.	Pressurized Product	Handheld equipment	0.3 g/ can	Cannot be calculated from label	Not stated on label	21
Inside trees	Termites, Carpenter ants	Pressurized Product	Handheld equipment	0.3 g/ can	Cannot be calculated from label	Not stated on label	21
Use-Site Category 27: Ornamentals Outdoor							
Outdoor ornamentals	Black vine weevils	SU	Ground: Airblast or Field Sprayer	27 g /ha	(81 g / ha)	3	7
		EC					
Inside trees	Termites, carpenter ants	Pressurized Product	Handheld equipment	0.3 g/ can	Cannot be calculated	Not stated on label	21
Aerial termite carton	Termites						
Use-Site Category 30: Turf							
Turf (sod, golf course, home, industrial and commercial lawns)	Ants	SU	Ground: field sprayer	37 g /ha	(148 g /ha)	4	7
Use-site Category 13 and 14: Terrestrial Feed Crops and Terrestrial Food Crops							
Legume Vegetables including Soybean	Soybean aphid, pea aphid, bean aphid	EC	Ground: field sprayer Aerial	Ground: 27.96 g /ha Aerial: 9.96 g /ha	(Ground: 83.88 g /ha) (Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	7
	Western bean cutworm			Ground: 22.44 g /ha Aerial: 9.96 g /ha	(Ground: 67.32 g /ha Aerial: 19.92 g /ha)		4
Carrots	Carrot rust fly, carrot weevil	EC	Ground: Field sprayer	9.96 g /ha	(29.88 g /ha)	3	7
		SU		10.13 g /ha	(30.39 g /ha)		

Site(s)	Pest(s)	Formulation Type[1]	Application Methods and Equipment	Application rate (a.i./ha)[2]		Maximum Number of Applications per year[2]	Minimum Interval Between Applications (days)[2]
				Maximum Single	Maximum Cumulative		
Potatoes	Armyworm, European corn borer	EC	Ground: field sprayer Aerial	9.96 g /ha	(Ground: 29.88 g /ha) (Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	4
		SU	Ground: Field sprayer	10.13 g /ha	(30.39 g /ha)	3	
	Colorado potato beetle	EC	Ground: field sprayer Aerial	Ground: 15 g /ha Aerial: 9.96 g /ha	(Ground: 30 g /ha) (Aerial: 19.92 g/ha)	Ground: (3 at 9.96 g a.i./ha or 2 at 15 g a.i./ha) Aerial: 2	7
		SU	Ground: Field sprayer	15.25 g /ha	(30.50 g /ha)	(3 at 10.13 g a.i./ha or 2 at 15.25 g a.i./ha)	
	Potato flea beetle, potato leafhopper, tarnished plant bug, and tuber flea beetle	EC	Ground: field sprayer Aerial	Ground and aerial: 9.96 g /ha	(Ground: 29.88 g /ha) (Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	
		SU	Ground: Field sprayer	10.13 g /ha	(30.39 g /ha)	3	
Crop Group 1C Tuberous and Corm Vegetables Subgroup	Diamondback moth, cabbage looper, black cutworm, imported cabbageworm, swede midge, corn earworm, tobacco hornworm, tomato hornworm, variegated cutworm, fall armyworm, beet armyworm, Liriomyza leafminers, Psyllids	SU	Ground: field sprayer Aerial	Ground and aerial: 25 g /ha	(Ground and aerial: 50 g /ha)	2	7
Crop Group 6 Legume Vegetables	Soybean aphid, Pea aphid, bean aphid, Western bean cutworm, bean leaf beetle, cabbage looper, armyworm, fall armyworm, beet armyworm, corn earworm, European corn borer	SU	Ground: field sprayer Aerial	Ground and aerial: 25 g /ha	(Ground: 75 g /ha) (Aerial: 25 g /ha)	Ground: 3 Aerial: 1	Ground: 7 Aerial: Not applicable
Field peas	Pea leaf weevil	SU	Ground: Field sprayer	10.13 g /ha	(30.39 g /ha)	3	7

Site(s)	Pest(s)	Formulation Type[1]	Application Methods and Equipment	Application rate (a.i./ha)[2]		Maximum Number of Applications per year[2]	Minimum Interval Between Applications (days)[2]
				Maximum Single	Maximum Cumulative		
		EC	Ground: field sprayer Aerial	9.96 g /ha	(Ground: 29.88 g /ha) (Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	4
	Pea leaf weevil, Western bean cutworm						
	Soybean aphid, pea aphid, bean aphid			Ground: 27.96 g /ha Aerial: 9.96 g /ha	(Ground: 83.88 g /ha Aerial: 19.92 g /ha)		7
Soybean, succulent and dry edible beans, succulent and dry peas, fava beans (broad beans) and chickpeas	Bean leaf beetle	EC	Ground: field sprayer Aerial: fixed-wing or rotary aircraft	Ground: 27.96 g /ha Aerial: 9.96 g /ha	(Ground: 83.88 g /ha) (Aerial: 19.92 g /ha)		4
Soybeans, dry peas, chickpeas and lentils	Grasshoppers			Ground and aerial: 9.96 g a.i./ha	(Ground: 29.88 g /ha Aerial: 19.92 g /ha)		
Soybeans, Succulent and Dry Edible Beans, Fava Beans, Lentils	Lygus bugs						
Soybeans, Succulent and Dry Edible Beans, Succulent and Dry Peas, Chickpeas, Lentils	Cutworms						
Legumes (Crop group 6 including soybeans)	Soybean aphid, pea aphid, bean aphid	SU	Ground: Field sprayer	28.43 g /ha	(85.29 g /ha)	3	7
	Western bean cutworm			22.81 g /ha	(68.43 g /ha)		4

Site(s)	Pest(s)	Formulation Type[1]	Application Methods and Equipment	Application rate (a.i./ha)[2]		Maximum Number of Applications per year[2]	Minimum Interval Between Applications (days)[2]
				Maximum Single	Maximum Cumulative		
Peas, dry: peas (*Pisum* spp.) pigeon pea	Cutworms, grasshoppers, pea aphids	SU	Ground: Field sprayer	10.13 g /ha	(30.39 g /ha)	3	4
	Bean leaf beetle			28.43 g /ha	(85.29 g/ ha)		
		EC	Ground: field sprayer Aerial	Ground: 27.96 g /ha Aerial: 9.96 g /ha	(Ground: 83.88 g /ha) (Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	
	Cutworms, grasshoppers			9.96 g a.i./ha	(Ground: 29.88 g /ha) (Aerial: 19.92 g /ha)		
	Soybean aphid, pea aphid, bean aphid			Ground: 27.96 g /ha Aerial: 9.96 g /ha	(Ground: 83.88 g /ha) (Aerial: 19.92 g /ha)		7
	Western bean cutworm			Ground: 22.44 g /ha Aerial: 9.96 g /ha	(Ground: 67.32 g /ha) (Aerial: 19.92 g /ha)		4
Soybeans	Soybean aphids, bean leaf beetle	SU	Ground: Field sprayer	28.43 g /ha	(85.29 g/ ha)	3	
	Grasshoppers, cutworms, lygus bugs			10.13 g /ha	(30.39 g /ha)		
		EC	Ground: field sprayer Aerial	Ground and aerial: 9.96 g a.i./ha	(Ground: 29.88 g /ha Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	
	Bean leaf beetle			Ground: 27.96 g /ha Aerial: 9.96 g /ha	(Ground: 83.88 g /ha) (Aerial: 19.92 g /ha)		
	Soybean aphid, pea aphid, bean aphid						7
	Western bean cutworm			Ground: 22.44 g /ha Aerial: 9.96 g /ha	(Ground: 67.32 g /ha) (Aerial: 19.92 g /ha)		4

Site(s)	Pest(s)	Formulation Type[1]	Application Methods and Equipment	Application rate (a.i./ha)[2]		Maximum Number of Applications per year[2]	Minimum Interval Between Applications (days)[2]
				Maximum Single	Maximum Cumulative		
Soybeans, dried shelled beans (*Phaseolus* spp., *Lupinus* spp., *Vigna* spp., dry fava beans, dry lablab beans and chickpeas)	Bean leaf beetle, soybean aphids	SU	Ground: field sprayer Aerial	1Ground and aerial: 9.08 g /ha	(Ground and aerial: 57.24 g/ ha)	3	7
Apples	Apple aphid, apple brown bug, apple leaf midge, codling moth, fruit tree leafroller, oblique banded leafroller, pale apple leafroller, spotted tentiform leafminer, white apple leafhopper, winter moth	EC	Ground: Airblast Sprayer	9.96 g /ha	(29.88 g /ha)		
		SU		10.13 g /ha	(30.39 g/ ha)		
	Plum curculio, tarnished plant bug, woolly apple aphid	EC		12.48 g /ha	(37.44 g/ ha)		
		SU		12.69 g /ha	(38.07 g/ ha)		
Barley, oats, wheat	Grasshoppers	EC	Ground: field sprayer Aerial	Ground and aerial: 9.96 g /ha	(Ground: 29.88 g /ha) (Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	
		SU	Ground: field sprayer	10.13 g /ha	(30.39 g/ ha)	3	
Crop Group 15 Cereal Grains	Armyworm	EC	Ground: field sprayer Aerial	Ground and aerial: 9.96 g /ha	(Ground: 29.88 g /ha) (Aerial: 19.92 g /ha)	Ground: 3 Aerial: 2	4
		SU	Ground equipment	10.13 g /ha	(30.39 g/ ha)	3	

Site(s)	Pest(s)	Formulation Type[1]	Application Methods and Equipment	Application rate (a.i./ha)[2]		Maximum Number of Applications per year[2]	Minimum Interval Between Applications (days)[2]
				Maximum Single	Maximum Cumulative		
Corn	Armyworm	EC	Ground: field sprayer Aerial	Ground and aerial: 24.96 g /ha	(Ground: 74.88 g/ ha) (Aerial: 49.92 g/ ha)	Ground: 3 Aerial: 2	4
		SU	Ground equipment	25.0 1 g /ha	(75.0 3 g /ha)	3	
	Cutworms, fall armyworm	EC	Ground: field sprayer Aerial	Ground and aerial: 9.96 g /ha	(Ground: 29.88 g/ ha) (Aerial: 19.92 g/ ha)	Ground: 3 Aerial: 2	
		SU	Ground equipment	25.01 g /ha	(75.03 g/ ha)	3	
	European corn borer, corn earworm	EC	Ground: field sprayer Aerial	ground and aerial: 22.44 g /ha	(Ground: 67.32 g/ ha) (Aerial: 44.88 g/ ha)	Ground: 3 Aerial: 2	
		SU	Ground equipment	22.81 g /ha	(68.43 g/ ha)	3	
	European corn borer, corn earworm, western bean cutworm, armyworm	SU	Ground: field sprayer Aerial	Ground: 25 g /ha	(50.0 g/ ha)	2	7
		EC		Ground and aerial: 9.96 g /ha	(Ground: 29.88 g/ ha) (Aerial: 19.92 g/ ha)	Ground: 3 Aerial: 2	4
	Western bean cutworm	EC	Ground: field sprayer Aerial	22.44 g /ha	(Ground: 67.32 g/ ha) (Aerial: 44.88 g/ ha)		
		SU	Ground equipment - foliar	22.81 g /ha	(68.43 g/ ha)	3	
Use-site Category 21 and 27: Structures and Ornamental Outdoors							
Inside stumps, utility poles, fences	Termites, carpenter ants	Pressurised product	Handheld equipment	0.3 g/ can	Cannot be calculated	Not stated on label	21

Site(s)	Pest(s)	Formulation Type[1]	Application Methods and Equipment	Application rate (a.i./ha)[2]		Maximum Number of Applications per year[2]	Minimum Interval Between Applications (days)[2]
				Maximum Single	Maximum Cumulative		
Use-site Category 7, 13 and 14: Terrestrial Non-food and Non-feed Seed and Fibre Crops, Terrestrial Feed Crops and Terrestrial Food Crops							
Canola	Cabbage seedpod weevil (adults)	EC	Ground: field sprayer Aerial	Ground and aerial: 9.96 g /ha	(Ground and aerial: 9.96 g /ha)	1	Not applicable
	Cutworm, crucifer flea beetle, lygus bug, imported cabbageworm, diamondback moth larvae, cabbage looper, bertha armyworm, swede midge	EC	Ground: field sprayer Aerial	Ground and aerial: 9.96 g /ha	(Ground: 29.88 g/ ha) (Aerial: 9.96 g/ha)	[Ground: 3] Aerial: 1	Ground: 7 Aerial: Not applicable
	Grasshoppers	SU	Ground: Field sprayer	10.13 g /ha	(30.39 g /ha)	3	7
	Cutworm, imported cabbageworm, diamondback moth larvae, cabbage looper, bertha armyworm, crucifer flea beetle, lygus bug						
Flax	Grasshoppers	EC	Ground: field sprayer Aerial	Ground and aerial: 9.96 g /ha	(Ground: 29.88 g/ ha) (Aerial: 9.96 g/ha)	Ground: 3 Aerial: 1	Ground: 7 Aerial: Not applicable
		SU	Ground: Field sprayer	10.13 g/ ha	(30.39 g/ ha)	3	7
	Cutworms	EC	Ground: field sprayer Aerial	Ground and aerial: 9.96 g /ha	(Ground: 29.88 g/ ha) (Aerial: 9.96 g/ha)	Ground: 3 Aerial: 1	Ground: 7 Aerial: Not applicable

Site(s)	Pest(s)	Formulation Type[1]	Application Methods and Equipment	Application rate (a.i./ha)[2]		Maximum Number of Applications per year[2]	Minimum Interval Between Applications (days)[2]
				Maximum Single	Maximum Cumulative		
Mustard	Cabbage seedpod weevil (adults)	EC	Ground: field sprayer Aerial	Ground and aerial: 9.96 g /ha	(Ground and aerial: 9.96 g /ha)	1	Not applicable
	Cutworm, crucifer flea beetle, lygus bug, imported cabbageworm, diamondback moth larvae, cabbage looper, bertha armyworm	EC	Ground: field sprayer Aerial	Ground and aerial: 9.96 g /ha	(Ground: 29.88 g/ ha) (Aerial: 9.96 g/ha)	Ground: 3 Aerial: 1	Ground: 7 Aerial: Not applicable
	Crucifer flea beetle, lygus bug, imported cabbageworm, diamondback moth larvae, cabbage looper, bertha armyworm	SU	Ground: Field sprayer	10.13 g /ha	(10.13 g /ha)	3	7
	Grasshoppers	EC	Ground: field sprayer Aerial	Ground and aerial: 9.96 g /ha	(Ground: 29.88 g/ ha Aerial: 9.96 g/ha)	[Ground: 3] Aerial: 1	Ground: 7 Aerial: Not applicable
		SU	Ground: Field sprayer	10.13 g /ha	(30.39 g /ha)	3	7
Crop Group 20A Rapeseed Subgroup Crop Group 20B Sunflower Subgroup	Flea beetle, lygus bug, imported cabbageworm, diamondback moth, cabbage looper, bertha armyworm, grasshoppers, sunflower beetle	SU	Ground: field sprayer Aerial	11.25 g /ha	(33.75 g/ ha)	Ground: 3 Aerial: 1	Ground: 7 Aerial: Not applicable
	Cabbage seedpod weevil (adults)				(Ground and aerial: 11.25 g/ ha)	1	Not applicable
Sunflower	Lygus Bugs	EC	Ground: field sprayer Aerial	Ground and aerial: 9.96 g /ha	(Ground: 29.88 g/ ha) (Aerial: 9.96 g/ha)	Ground: 3 Aerial: 1	Ground: 7 Aerial: Not applicable
		SU	Ground: Field sprayer	10.13 g /ha	(30.39 g /ha)	3	7
	Sunflower beetle	EC	Ground: field sprayer Aerial	Ground: 7.56 g /ha Aerial: 9.96 g /ha	(Ground: 22.68 g /ha) (Aerial: 9.96 g /ha)	Ground: 3 Aerial: 1	Ground: 7 Aerial: Not applicable
		SU	Ground: Field sprayer	7.69 g /ha	(23.07 g/ ha)	3	7

[1] SN=Solution, EC=Emusifiable Concentrate or Emulsion, SU= Suspension

[2] All information is derived from registered product labels, except for information provided by registrants which is indicated by [ ], and data calculated by PMRA is indicated by ( ).

Appendix III Toxicity Profile and Endpoints for Health Risk Assessment

Table 1 Toxicology Endpoints for the Human Health Risk Assessment of Lambda-Cyhalothrin

Exposure Scenario	RfD	Study Point of Departure	CAF[1] or Target MOE
Acute Dietary	ARfD = 0.0006 mg/kg bw	$BMDL_{20}$ = 0.19 mg/kg bw acute oral neurotoxicity study with lambda-cyhalothrin in rats (↓ motor activity)	300
Chronic Dietary	ADI = 0.0003 mg/kg bw/day	NOAEL = 0.1 mg/kg bw/day 1-year oral study with lambda-cyhalothrin in dogs (neurotoxic signs, liquid feces, ↓ rel testes wt)	300
Short-, Intermediate- and Long-Term Dermal	-	NOAEL = 10 mg/kg bw/day 21-day dermal study with lambda-cyhalothrin in rats (neurotoxic signs, ↓ bw, ↓ rel ovary wt, seminal vesicle atrophy)	300
Short-, Intermediate- and Long-Term Inhalation	-	NOAEL = 0.08 mg/kg bw/day 21-day inhalation toxicity study with lambda-cyhalothrin in rats (neurotoxic signs, ↓ bw, ↑ liver wt, ↓ cholesterol, punctate foci of cornea)	300
Short- and Intermediate-Non-Dietary Incidental Oral Ingestion	-	$BMDL_{20}$ = 0.19 mg/kg bw acute oral neurotoxicity study with lambda-cyhalothrin in rats (↓ motor activity)	300
Aggregate Risk – Oral	-	NOAEL = 0.1 mg/kg bw/day 1-year oral study with lambda-cyhalothrin in dogs (neurotoxic signs, liquid feces, ↓ rel testes wt)	300
Aggregate Risk – Inhalation	-	NOAEL = 0.08 mg/kg bw/day 21-day inhalation toxicity study with lambda-cyhalothrin in rats (neurotoxic signs, ↓ bw, ↑ liver wt, ↓ cholesterol, punctate foci of cornea)	300
Aggregate Risk – Dermal	-	NOAEL = 10 mg/kg bw/day 21-day dermal study with lambda-cyhalothrin in rats (neurotoxic signs, ↓ bw, ↓ rel ovary wt, seminal vesicle atrophy)	300
Carcinogenicity [2]	$q_1^* = 2.66 \times 10^{-2}$ (mg/kg bw/day)$^{-1}$ based on the combined incidence of uterine leiomyoma and leiomyosarcoma in female mice treated orally with cyhalothrin.		

[1] CAF (Composite assessment factor) refers to the total uncertainty and PCPA factors for dietary and residential risk assessment. MOE refers to the target margin of exposure for occupational assessment.

[2] Since an oral study was used to determine the q_1^*, a dermal absorption factor of 14% was used in route-to-route extrapolation.

Table 2 Toxicology Profile for Lambda-Cyhalothrin

Note: Effects noted below are known or assumed to occur in both sexes unless otherwise noted: in such cases, sex-specific effects are separated by semi-colons. Effects on organ weights are known or assumed to reflect changes in both absolute weight and relative (to body weight) weight, unless otherwise noted.

Toxicokinetic and Metabolism Studies	
Study/Species	**Results/Effects**
Absorption, Distribution – Gavage (Lambda-cyhalothrin in corn oil) Wistar Rat PMRA# 2413362	**Single High-Dose:** **Absorption:** Rapidly absorbed; the half-life ($T_{1/2}$) for absorption was 0.87 hr. The bioavailability of lambda-cyhalothrin was 67.4%. Peak concentrations in plasma (15.7µg/mL) were observed 2.7 hrs post-dosing. Elimination from plasma was biphasic and followed a two-compartment open model. The elimination half-life in plasma was 10.3 hrs, with lambda-cyhalothrin efficiently distributed to all tissues examined. **Distribution:** Analysis of the tissue concentration time-course revealed long elimination half-lives in all tissues examined ($T_{1/2}$ = 13 to 35 hrs). High concentrations of lambda-cyhalothrin were detected in all regions of the brain (C_{max} of 12-24 µg/g). Peak concentrations in nervous tissue and testes were noted within 3 hrs of administration and were generally higher than peak concentrations in plasma. The highest concentrations were noted in the hypothalamus ($T_{1/2}$ = 35 hrs), myenteric plexus ($T_{1/2}$ = 23 hrs) and vas deferens ($T_{1/2}$ = 16 hrs).
Absorption, Distribution, Metabolism, Elimination – Gavage (Cyhalothrin in corn oil) Alpk Wistar Rat PMRA# 1248962, 1248963, 2235663	**Single Low-Dose/Single High-Dose ([^{14}C]-cyano-3-phenoxybenzyl or [^{14}C]-cyclopropyl or [^{14}C]-methine-label):** **Absorption:** Rapidly but incompletely absorbed (~55%) following administration of either dose. Peak concentrations in blood were noted between 4 hrs and 7 hrs post-dosing with each dose, label position or sex. The $T_{1/2}$ for elimination in blood ranged from 6.7 hrs to 13.7 hrs. At 48 hrs, the concentration of radioactivity in blood was 10% of peak values. The majority of radioactivity in the blood was associated with plasma. **Distribution**: Distribution of radioactivity to various tissues was similar for each dose level, label position or sex: white fat > brown fat > female gonads > liver > other tissues. The radioactivity in fat was identified as unchanged parent compound. The half-life in peri-renal white fat could not be determined; the elimination $T_{1/2}$ of cyhalothrin in white fat was estimated to be 23 days. The $T_{1/2}$ of cyhalothrin in brown fat was 32 hrs in either sex. Radiolabel was detected in most tissues 7 days following exposure due to the retention and slow depletion of cyhalothrin from fat (predominantly white fat). Seven days after administration of 1 mg/kg bw cyclopropyl label, concentrations of radioactivity in white fat in ♀ (0.3 µg/g) were almost double that of ♂ (0.17 µg/g). A similar pattern was observed with ♂ (6.4 µg/g) and ♀ (11.5 µg/g) receiving 25 mg/kg bw phenoxybenzyl-label. Brain levels were quantified (0.1 to 0.2 µg/g) following the high-dose administration only.

	Metabolism: Cyhalothrin was extensively metabolized by hydrolysis of the ester bond, resulting in the formation of cyclopropylcarboxylic acid (and its glucuronide conjugate (~50% of urinary ^{14}C material) and small amounts (<5%) of 3-phenoxybenzoic acid (3-PBA) and 3,4'-hydroxyphenoxybenzoic acid (and sulphate conjugates). **Elimination:** Elimination was similar for either sex. Approximately 20% to 40% of the administered dose was eliminated in urine (with the remainder eliminated in feces) up to 7 days following exposure. The majority of radioactivity was recovered within the first 24 hrs, except for high-dose animals dosed with the cyclopropyl-labelled material. Radiolabel was not detected in expired air. Parent compound was not detected in urine or bile. Unabsorbed material was eliminated in feces as unchanged parent compound.
Distribution – Gavage (Cyhalothrin in corn oil) Alpk Wistar Rat PMRA# 2235662	**Single High-Dose ([^{14}C]-cyclopropyl-label):** **Distribution:** In ♀, peak concentrations in most tissues were noted 7 hrs post-dosing, with the highest levels detected in brown fat (8.3 µg/g) and peri-renal white fat (3.1 µg/g). In ♂, peak tissue concentrations were generally observed 17 hrs post-dosing, with the highest levels also noted in brown fat (15.3µg/g) and peri-renal fat (9.6 µg/g). There were no sex-related differences in the elimination of radioactivity from tissues, with the exception of gonads and fat. Radioactivity was eliminated from brown fat with a half-life of 18 hrs in ♂, and 34 hrs in ♀. Concentrations of radioactivity in peri-renal white fat, although initially lower than brown fat, did not decline markedly from their peak concentrations during this study. The half-life in peri-renal white fat could not be determined in this investigation. The elimination $T_{1/2}$'s for cyhalothrin in gonads were 7 hrs for ♂ (testes) and 25 hrs for ♀ (ovary). After 96 hrs, radioactivity levels remained highest in fat (brown fat/peri-renal white fat = 3.2/8.9 µg/g in ♀; 2.7/5.4 µg/g ♂) and ovary (1.7 µg/g). Levels of radioactivity in brain, spleen and muscle were below the limit of detection in both sexes.
Distribution, Elimination – Gavage (Cyhalothrin in corn oil) Alpk Wistar Rat PMRA# 1248968, 2448118	**Single Low-Dose ([^{14}C]-cyclopropyl-label):** **Distribution**: Distribution in selected tissues was comparable in animals administered either cyhalothrin or lambda-cyhalothrin: fat > liver > kidney > blood. The mean concentration of lambda-cyhalothrin or cyhalothrin in fat was 0.25µg/g or 0.26 µg/g, respectively. **Elimination:** For cyhalothrin and lambda-cyhalothrin, >90% of the administered dose was eliminated within 72 hrs (22% to 28% in urine; 63% to 68% in feces). Unchanged parent compound was not detected in urine with either compound.
Absorption, Distribution, Elimination – Gavage (Cyhalothrin in corn oil)	**Repeated Low-Dose ([^{14}C]-benzyl or [^{14}C]-cyclopropyl label):** **Absorption:** Cyhalothrin was incompletely absorbed; 30% to 50% of the administered dose was absorbed with either label position.

Alpk Wistar Rat PMRA# 1248964, 1248961	**Distribution:** Two days post-dosing, fatty tissue demonstrated significant accumulation of radioactivity (levels in white fat were up to 88-fold higher than blood). Lungs, liver, kidney and gonads also demonstrated concentrations of radioactivity which were 2- to 7-fold higher than blood. Seven days after the last dose, radioactivity levels declined significantly in the latter tissues, though levels remained higher than blood. Levels of radioactivity in white fat did not decline significantly 7 days following the last exposure, primarily due to the retention of parent compound. The concentration of radioactivity in white fat was 3.3µg/g, 7 days following the last dose. The elimination $T_{1/2}$ of cyhalothrin in fat was 23 days. Levels in brain were up to 0.02 µg/g at 2 and 5 days post-dosing and dropped to 0.01 µg/g at 7 days post-dosing. **Elimination:** Approximately 90% of the total cumulative dose was eliminated in the urine and feces within 7 days of the last exposure. Females eliminated more of the benzyl-label in the urine (53%) than males (48%), and males eliminated less of the cyclopropyl-label (30%) in the urine than the benzyl label.
Absorption, Metabolism – Gavage (Lambda-Cyhalothrin in corn oil or diet-slurry in water) Pregnant or Non-Pregnant Alpk Wistar Rat PMRA# 2235659	**Single Low-Dose ([^{14}C]-cyano-3-phenoxybenzyl or [^{14}C]-cyclopropyl label):** **Absorption:** Following gavage dosing, there were no significant differences in total systemic exposure between pregnant and non-pregnant rats. Peak plasma concentrations of radioactivity (1.08-1.26 µg/g) were noted 8 to 12 hrs post-dosing and decreased to 0.05 to 0.11 µg/g, 48 hrs post-exposure. Administration of diet slurry in non-pregnant rats resulted in more rapid and extensive absorption, compared to gavage administration in pregnant or non-pregnant rats. Peak plasma concentrations of radioactivity were greater (1.82-3.29 µg/g) and observed at an earlier time point (1 hr) after dietary dosing; plasma levels declined to 0.08 µg/g, 48 hrs post-exposure. **Metabolism:** Following administration by gavage or diet slurry, the metabolites identified in plasma were: 3-PBA, 3-4`-hydroxyphenoxybenzoic acid and 3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropane carboxylic acid (TFP acid), in addition to parent compound.
Absorption, Metabolism – Gavage (Lambda-Cyhalothrin in corn oil, CMC or diet-slurry in water) Alpk Wistar Rat PMRA# 2235660	**Single Low-Dose ([^{14}C]-cyclopropyl label):** **Absorption:** Lambda-cyhalothrin was absorbed more rapidly following administration in the diet slurry; peak plasma concentrations of lambda-cyhalothrin were noted 1 hr following administration. Peak plasma concentrations of lambda-cyhalothrin with CMC vehicle were noted 2 hrs following exposure. Peak plasma concentrations of lambda-cyhalothrin were noted 8 hrs following administration in corn oil. The AUC_{0-48} values for radioactivity were similar for the corn oil or CMC vehicle, and up to 1.7-fold higher for the dietary slurry. The AUC_{0-48} for lambda-cyhalothrin was comparable in all groups. **Metabolism:** The parent compound accounted for only a small percentage of the total

	radioactivity in plasma suggesting extensive metabolism of lambda-cyhalothrin.
Absorption, Metabolism – Diet (Lambda-Cyhalothrin) Alpk Wistar Rat PMRA# 2235661	**Single Low-Dose ([^{14}C]-cyano-3-phenoxybenzyl label):** **Absorption:** Lambda-cyhalothrin was rapidly absorbed, with peak concentrations of parent compound in blood (0.11µg/mL) noted 4 hrs following the initiation of feeding; levels declined to 0.06 µg/mL at 24 hrs. Exposure to lambda-cyhalothrin was consistent throughout the feeding period. The peak concentration of total radioactivity in blood (1.91µg/mL) was noted 24 hrs after initiation of dosing. **Metabolism:** The parent compound accounted for only a small percentage of the total radioactivity in blood suggesting that lambda-cyhalothrin is extensively metabolized within 24 hrs.
119-Day Bioaccumulation Study – Gavage (Cyhalothrin in corn oil) Alpk Wistar Rat PMRA# 1248967, 2448119	**[^{14}C]-Cyclopropyl label:** Concentrations of radioactivity in blood (0.1 to 0.59 µg/g) remained low during dosing, while levels in fat increased during treatment to up to 10 µg/g (day 119). Radioactivity levels in liver and kidney reached a plateau (1.2 to 2.5 µg/g) after day 70 of treatment, and fell rapidly after cessation of exposure. Levels in fat declined slowly after cessation of treatment by apparent first-order kinetics; the predominant compound detected in fat was unchanged parent compound. The $T_{1/2}$ for the elimination of radioactivity in fat was 31 days. Radioactivity was detected in liver following cessation of exposure. Elimination in this tissue appeared to parallel that of fat, likely due to the slow release of radioactivity from fat and redistribution to liver prior to elimination. **Potential for bioaccumulation**
Absorption, Distribution – Gelatin Capsule or Diet (Lambda-Cyhalothrin) Beagle Dog PMRA# 2235658	**Single Low-Dose:** **Absorption:** Administration via capsule resulted in higher peak plasma levels, compared to dietary administration, as well as more rapid absorption. Peak concentrations in plasma following capsule administration (52 µg/g) were noted 2 hrs post-dosing. Acute dietary administration resulted in peak plasma levels (20 ng/mL), 2 hrs to 6 hrs post-dosing. **Distribution**: Following a single dose via capsule or diet, concentrations in plasma declined rapidly to below the limit of detection within 8 hrs to 12 hrs after dosing. The elimination $T_{1/2}$ in plasma was 2 hrs, irrespective of the dosing regimen. The mean AUC was comparable between dosing regimens.
Absorption, Metabolism, Elimination – Gavage (Cyhalothrin in corn oil) Beagle Dog PMRA# 1248969, 2448119	**Single Low-Dose/Single High-Dose ([^{14}C]-cyano-3-phenoxybenzyl or [^{14}C]-cyclopropyl label):** **Phenoxybenzyl-Label:** **Absorption:** Approximately 80% of the administered dose was absorbed. At 1 mg/kg bw, radioactivity in plasma increased steadily to a peak concentration of 1.34 µg equiv/mL at approximately 6 hrs post-dosing, though some animals demonstrated a secondary peak later. The time-of-peak concentration ranged from 2 hrs to 12 hrs. At 10 mg/kg bw, the peak concentration of radioactivity in plasma was 4.11 µg equiv/mL at 12 hrs post-dosing, though some animals also demonstrated a

	secondary peak later. Plasma concentrations declined mono-exponentially at both dose levels, 24 hrs after dosing. The radioactivity in blood was associated with plasma. **Metabolism:** Absorbed material was extensively metabolized by cleavage of the ester bond. The phenoxybenzyl moiety was further metabolized, resulting in the following main metabolites in urine: N-(3-phenoxbenzoyl) glycine, 3-(4-hydroxyphenoxy) benzoic acid, 3-phenoxbenzoyl glucuronide and 3-(4-sulphonyloxyphenoxy)benzoic acid. Other conjugated metabolites were also identified. The cyclopropane acid moiety was extensively metabolized to produce 11 additional metabolites which included the cyclopropane acid glucuronide and other conjugated metabolites. **Elimination:** Elimination of radioactivity was initially rapid, with most of the administered dose eliminated within the first 48 hrs. However, elimination remained incomplete after 7 days, with mean recovery around 85%. Absorbed material was eliminated via kidney and bile. The metabolites noted above accounted for approximately 60% of the radioactivity recovered in urine at 24 hrs. Relative proportions of the various metabolites in urine were dose-dependent. During the first 24 hrs following exposure, radioactivity in the feces of animals administered either dose was recovered primarily as unchanged parent compound, though metabolites were also present. From 24 hrs to 48 hrs post-dosing, metabolites formed a greater proportion (87%) of the radioactivity recovered in feces. **Cyclopropyl-Label** **Absorption:** Approximately 50% of the administered dose was absorbed. Peak blood levels were observed 4 hrs (0.7 µg equiv/mL) or 12 hrs (2.7 µg equiv/mL) following exposure to 1 or 10 mg/kg bw, respectively. **Metabolism:** Following exposure, 12 metabolites were identified in urine; 23% identified as 3(2-chloro-3,3,3-trifluropropyl-enyl)-2,2-dimethylcyclopropane carboxylic acid and 43% identified as its glucuronide. Regardless of the dose or radiolabel position, the majority of radioactivity identified in feces was unchanged cyhalothrin. **Elimination:** Elimination remained incomplete after 7 days with mean recovery ranging from 89% to 93%. Approximately 19% of the administered dose was eliminated in urine and 68% was recovered in feces after 7 days regardless of dose. Absorbed material was eliminated via kidney and bile.

Acute Toxicity Studies	
Study/Species	**Results/Effects**
Acute Oral Toxicity – Gavage (Lambda-Cyhalothrin) Alpk Swiss Albino Mouse PMRA# 1248869	LD_{50} = 19.9 mg/kg bw (♂/♀) (in corn oil) **≥25 mg/kg bw (♂/♀):** piloerection, upward curvature of the spine, ataxia, salivation **High acute oral toxicity**
Acute Oral Toxicity – Gavage (Cyhalothrin) Alpk Swiss Albino Mouse PMRA# 1248867	LD_{50} = 36.7 mg/kg bw (♂) (in corn oil) LD_{50} = 62.3 mg/kg bw (♀) (in corn oil) **High acute oral toxicity**
Acute Oral Toxicity – Gavage (Lambda-Cyhalothrin) Wistar Rat PMRA# 2140998	LD_{50} = 528 mg/kg bw (♀) (in methylcellulose) **≥55 mg/kg bw (♀):** ↓activity, irritability, hunched back, tremors (continuous and intermittent), clonic convulsions, vocalization, splayed hindlimbs, incoordination, twitch, prone position, piloerection, salivation, ↓body temperature **Moderate acute oral toxicity**
Acute Oral Toxicity – Gavage (Lambda-Cyhalothrin) Albino Norway Rat PMRA# 2413381	LD_{50}= 75.9 mg/kg bw (♂) (in peanut oil) LD_{50}= 56.7 mg/kg bw (♀) (in peanut oil) **High acute oral toxicity**
Acute Oral Toxicity – Gavage (Cyhalothrin) Alpk Wistar Rat PMRA# 1248871	LD_{50} = 79 mg/kg bw (♂) (in corn oil) LD_{50} = 56 mg/kg bw (♀) (n corn oil) **High acute oral toxicity**

Acute Oral Toxicity – Gavage (Cyhalothrin) Alpk Wistar Rat PMRA# 1248867	LD_{50}= 243 mg/kg bw (♂) (in corn oil) LD_{50}= 144 mg/kg bw (♀) (in corn oil) **High acute oral toxicity**
Acute Dermal Toxicity (Lambda-Cyhalothrin) Alpk Wistar Rat PMRA# 1248872	LD_{50} = 632 mg/kg bw (♂) (in propylene glycol) LD_{50} = 696 mg/kg bw (♀) (in propylene glycol) **≥300 mg/kg bw (♂/♀):** ↓ activity, tiptoe gait, splayed gait, loss of stability, dehydration, urinary incontinence, upward curvature of the spine **Moderate acute dermal toxicity**
Acute Dermal Toxicity (Lambda-Cyhalothrin) Wistar Rat PMRA# 2140999	LD_{50} >2000 (♂/♀) (undiluted) **≥1000 mg/kg bw (♀):** bw loss, irritability, vocalization, hunched back, wounds, ↓ activity, incoordination, tremors, salivation, erythema (♀) **2000 mg/kg bw (♂/♀):** bw loss, liquid feces, splayed hindlimbs, piloerection (♂), mortality (♀) **Low acute dermal toxicity**
Acute Inhalation Toxicity – Nose-Only (Lambda-Cyhalothrin) Wistar Rat PMRA# 1215778	LC_{50} = 0.065 mg/L (♂/♀) **≥ 0.015 mg/L:** abnormal respiratory noise, ↑ response to touch **≥0.041 mg/L:** hunched posture, piloerection,↑ response to sound, splayed or tiptoe gait, ungroomed, sides pinched-in, chromodacryorrhea, subdued behavior **0.071 mg/L:** agitated behavior, ↓ righting reflex, salivation, flicking paws **Moderate acute inhalation toxicity**
Acute Inhalation Toxicity – Nose-Only (Lambda-Cyhalothrin) Sprague-Dawley Rat PMRA# 2141000	LC_{50} > 0.23 mg/L (♂/♀) **≥0.10 mg/L (♂/♀):** ↓ bw (day 1), clinical signs of toxicity on day 1 (labored respiration, hunched posture, piloerection, rough coat, ploughing, irritation of snout, subdued behavior, cold to touch, staggering) **≥0.19 mg/L (♂/♀):** rolling gait, dark foci and discoloration of lungs **0.23 mg/L (♂/♀):** pale ears, high-stepping gait, closed eyes, unsteady gait, tremors (♀)

	Moderate acute inhalation toxicity
Eye Irritation (Lambda-Cyhalothrin) New Zealand White Rabbit PMRA # 1248874	MAS = 3.8 MIS = 11.3 All scores were not zero by day 3. **Mild ocular irritant**
Eye Irritation (Lambda-Cyhalothrin) New Zealand White Rabbit PMRA # 2141002	MAS = 5.3 MIS = 14.7 Mean irritation score was > 0 at 48 hrs. **Mild ocular irritant**
Dermal Irritation (Lambda-Cyhalothrin) New Zealand White Rabbit PMRA# 2141004	MAS = 0.66 MIS = 0.66 Very slight erythema (score 1) noted in 2 animals 1 hr following patch removal. Erythema persisted in 1 animal up to 72 hrs; edema was also noted in this animal 24, 48 and 72 hrs following patch removal. Seven days following dermal exposure, irritation scores were zero. **Slight dermal irritant**
Dermal Sensitization – Local Lymph Node Assay (Lambda-Cyhalothrin) CBA/JRj Mouse PMRA# 2141006	Negative **Not a dermal sensitizer**

Dermal Sensitization – Maximisation Test (Lambda-Cyhalothrin) Dunkin Hartley Guinea-Pig PMRA# 1313909	Negative **Not a dermal sensitizer**

Subchronic Toxicity Studies	
Study/Species	**Results/Effects**
28-Day Oral Toxicity – Diet (Cyhalothrin) CD-1 Mouse PMRA# 2432408	**Supplemental (range-finding study)** **≥3.3/4.2 mg/kg bw/day (♂/♀):** piloerection (starting wk 1); emaciated appearance (♀) **≥13.5/15.2 mg/kg bw/day (♂/♀):** ↓ lymphocyte count (♂); ↑ hepatic APDM activity (♀) **309/294 mg/kg bw/day (♂/♀):** mortality, ↓ bw, ↓ fc, emaciated appearance, abnormal gait, hunched posture, ↑ respiration; ↓ bwg, ↓ mean total WBC count, ↑ neutrophils, ↓ MCV, ↑ APDM activity, ↓ abs testes wt (♂); salivation, ↓ abs brain wt, minimal centrilobular hepatocyte enlargement, ↑ ovary wt (♀)
28-Day Oral Toxicity – Diet (Cyhalothrin - PP563, 100% cis-isomer; PP564, 1:1 cis:trans isomer ratio) 4-Week Old Alpk Wistar Rat PMRA# 2432409, 2432410, 2448116, 2448119	**Supplemental** **≥2 mg/kg bw/day PP563 (♂/♀):** ↑ APDM activity, ↑ hepatic SER proliferation (♂); slight hypersensitivity to touch (♀) **≥10 mg/kg bw/day PP563 (♂/♀):** slight hypersensitivity to touch; high-stepping gait, slight hypersensitivity to sound (♂); piloerection, ↑ APDM activity (♀) **≥25 mg/kg bw/day PP563 (♂/♀):** ↓ lung wt, ↓ bwg, ↓ fc; ataxia, piloerection, hunched posture, ↓ abs heart wt, ↓ kidney wt, ↓ abs spleen wt (♂); high-stepping gait, ↑ SER proliferation, hypersensitivity to sound (♀) **≥50 mg/kg bw/day PP563, PP564 (♂/♀):** ↓ bwg (PP564), sensitivity to external stimuli, piloerection, ataxia, ↓ abs lung wt (PP564), ↓ abs thymus wt, ↑ APDM activity (PP564); salivation (PP563), ↓ plasma triglycerides, ↓ urinary protein (PP563), ↓ heart wt (PP564), ↓ abs spleen wt (PP564), ↓ abs kidney wt (PP564) (♂); ↓ food utilization, hunched posture, dose-related ↓ abs gonad wt (PP564), ovarian cyst in 1 animal (PP563) (♀) **75 mg/kg bw/day PP563, PP564 (♂/♀):** mortality (starting wk 1; PP563), loss of stability (PP563), staining around nose, thymic atrophy (PP563), vacuolation and differential staining of adrenal cortical cells (PP563), ↓ abs brain wt, ↓ abs adrenal wt, ↑ "adjusted for bw" liver wt; appeared weak, salivation (PP564), reproductive

	effects in 2 animals which died (incomplete spermatogenesis, epididymis devoid of sperm, ↓ seminal vesicle secretions, testes not descended) (PP563) (♂); salivation (PP563), convulsions (PP563), ↓ plasma triglycerides, ↓ abs kidney wt (PP563), ↓ abs spleen wt (PP563), ↓ abs pituitary wt, 1 animal which died had only 1 ovary, ↓ abs gonad wt (PP563), ↓ gonad wt "adjusted for bw" (PP563; PP564) (♀) Effects noted with PP564 were comparable to PP563 but less severe, suggesting that the cis-isomer has greater toxicity than the trans-isomer.
28-Day Oral Toxicity – Diet (Cyhalothrin) 5-Week Old Alpk Wistar Rat PMRA# 2432411, 2448119	**Supplemental** **≥2 mg/kg bw/day (♀):** ↓ bw, ↓ bwg (♀) **25 mg/kg bw/day (♂/♀):** ↑ hepatic APDM activity, ↑ hepatic SER proliferation, ↓ bw; ↓ bwg, ↑ rel liver wt (♂)
90-Day Oral Toxicity – Diet (Cyhalothrin) Alpk Wistar Rat PMRA# 1248878, 2448116	**NOAEL = 2.6 mg/kg bw/day (♂); > 15 mg/kg bw/day (♀)** **LOAEL = 14 mg/kg bw/day (♂)**, based on ↓ bwg, ↓ abs lung wt, ↓ MCH; ↓ bw, ↓ fc, ↑ hepatic APDM activity, ↓ plasma triglycerides, ↑ urinary glucose, ↑ hepatic SER proliferation, kidney nephrosis, interstitial mononuclear cell infiltration in prostate (♂); ↓ MCV (♀)
90-Day Oral Toxicity – Diet (Lambda-Cyhalothrin) Alpk Wistar Rat PMRA# 1248880, 1248884	**NOAEL = 2.5 mg/kg bw/day (♂/♀)** **LOAEL = 12.5 mg/kg bw/day (♂/♀)**, based on ↓ bwg, ↓ fc, ↑ liver wt, ↑ hepatic APDM activity; slight ↓ abs brain wt, ↓ testes wt (♂); ↑ ovary wt (♀)
6-Week Oral Toxicity – Gelatin Capsule (Lambda-Cyhalothrin) Beagle Dog PMRA# 2235652, 2235653, 2448129	**Supplemental (range-finding study)** **≥0.75 mg/kg bw/day (♂/♀):** fluid feces after dosing throughout treatment (♂/♀) **≥1.5 mg/kg bw/day (♂/♀):** ↓ activity; vomiting and/or regurgitation, slight tremors (♀) **≥3 mg/kg bw/day(♂/♀):** salivation; unsteady gait (♂) **4 mg/kg bw/day (♂/♀):** ↓ fc, bw loss, inappetence, thin appearance; ↓ epididymis wt, epididymal interstitial mononuclear cell infiltration (♂); thyroid hyperplasia (♀)

6-Month Oral Toxicity – Gelatin Capsule (Cyhalothrin) Beagle Dog PMRA# 1248887, 2448116, 2448130	**NOAEL not established** **LOAEL = 1 mg/kg bw/day (♂/♀)**, based on liquid feces in all animals immediately after dosing throughout treatment (dose-related ↑ incidence and severity) (♂/♀) **10 mg/kg bw/day (♂/♀):** ↓ fc, ↑ wc, unsteadiness, trembling, head shaking, muscular spasm, lack of coordination, salivation; bw loss in 1 animal, vomiting, collapse, stiff-limbs, frothing at the mouth, subdued behavior, vocalization, convulsions, ↑ liver wt (♂); ↓ ovary wt (♀)
1-Year Oral Toxicity – Gelatin Capsule (Lambda-Cyhalothrin) Beagle Dog PMRA# 1204024, 1141968, 2448117, 2448121, 2448129	**NOAEL = 0.1 mg/kg bw/day (♂/♀)** **LOAEL = 0.5 mg/kg bw/day (♂/♀)**, based on liquid feces (starting wk 1), ataxia; stiff hindlimbs and paw flick in 1 animal, convulsions, ↓ rel testes wt (♂); subdued behavior (♀) **3.5 mg/kg bw/day (♂/♀):** thin appearance, ataxia, ↓ fc, vomiting, broken/bleeding claws, incoordination, straddled gait, recumbency, severe whole body tremors, hyperesthesia, ↑ plasma triglycerides, ↑ liver wt; subdued behavior, ↓ rel testes wt, ↓ plasma cholesterol (♂)
1-Year Oral Toxicity – Gelatin Capsule (Lambda-Cyhalothrin) Beagle Dog PMRA# 2235655	**NOAEL not established** **LOAEL = 0.75 mg/kg bw/day (♂)**, based on ↓ fc, dermal scabs, wounds and scratches (possibly resulting from paresthesia); ↓ bw, ↓ bwg, dose-related liquid feces throughout treatment (♂); ↓ bwg (♀) **≥1.5 mg/kg bw/day (♂/♀):** regurgitation; ↓ bwg, dose-related liquid feces throughout treatment (♀) **3 mg/kg bw/day (♂/♀):** salivation, clinical signs of neurotoxicity after dosing starting wk 1 (↓ activity, ↓ stability, ↓ hindlimb function, shaking, reluctance to stand, splayed gait, stiffened gait, tremors, unsteady gait); recumbency with muscle fasciculations, depressed, sedated behavior (♂); ↓ bw (♀)
21-Day Dermal Toxicity (Lambda-Cyhalothrin in olive oil) Alpk Wistar Rat PMRA# 2191525, 2127972, 2448117	**Dermal NOAEL not established** **Dermal LOAEL = 1 mg/kg bw/day (♂)**, based on signs of paresthesia, namely ↑ upward curvature of the spine starting day 2 (♂) **Systemic NOAEL = 10 mg/kg bw/day** **Systemic LOAEL = 50 mg/kg bw/day (♂/♀)**, based on chromodacryorrhea, ↓ splay reflex; ↓ bw, ↓ fc, tip-toe gait, ↓ abs liver wt, ↓ stability, ↓ activity, bizarre behavior, salivation, splayed gait, paw flick, sides pinched-in, slight atrophy of spleen, moderate atrophy of seminal vesicles, dehydration (♂); transient ↓ bwg, ↓ plasma cholesterol, ↓ rel kidney wt, ↓ rel ovary wt, ↓ splay reflex, sides pinched-in (♀) **100 mg/kg bw/day (♂):** mortality (day 4) (♂)

21-Day Dermal Toxicity (Cyhalothrin in PEG 300) New Zealand White Rabbit PMRA# 1248888, 1204026	**Dermal NOAEL (abraded/non-abraded) not established (♂/♀)** **Dermal LOAEL (abraded/non-abraded) = 10 mg/kg bw/day (♂/♀)**, based on desquamation, erythema, wrinkling, cracking, scabbing, thickening, hair loss, reddening (♂/♀) **Systemic NOAEL (abraded/non-abraded) = 100 mg/kg bw/day (♂/♀)** **Systemic LOAEL (abraded/non-abraded) = 1000 mg/kg bw/day (♂/♀)**, based on ↓ fc, ↓ gonad wt, bw loss, ↓ bw (starting wk 1); ↓ pituitary wt, clonic convulsions, labored respiration, cyanosed mucous membranes and eyes, downward curvature of the spine (♂); splayed gait, leg sores, cysts, ↓ Hgb, ↓ Hct (♀)
21-Day Inhalation Toxicity – Nose-Only (Lambda-Cyhalothrin; aerosol) Alpk Wistar Rat PMRA# 1124600, 2448120, 2448117	**NOAEL = 0.08 mg/kg bw/day (0.3 µg/L) (♂/♀)** **LOAEL = 0.9 mg/kg bw/day (♂/♀)**, based on ↓ bw, ↓ bwg, ↓ fc, respiratory noise, tail erection, lacrimation, salivation, dose-related ↑ incidence of punctate foci in cornea, ↑ urine specific gravity, ↓ urine volume; paw flick, splayed gait, ↓ urine protein, ↑ rel liver wt (♂); ↓ plasma albumin, ↓ plasma protein, ↓ platelets, ↓ plasma cholesterol, ↓ abs liver wt (♀) **4.5 mg/kg bw/day (♂/♀):** ↓ activity, head flick, auditory hypoesthesia, ↓ righting reflex, sides pinched-in, ↓ splay reflex, ↓ visual placing response, slight ↓ abs brain wt; tiptoe gait, ↓ plasma triglycerides, dark/red areas in lungs, ↓ foot withdrawal, shaking, ↓ WBC, ↓ lymphocytes, ↑ rel kidney wt, ↓ abs liver wt, ↓ abs lung wt (♂); ungroomed appearance, paw flick, splayed gait, ↑ AST, ↑ ALP, ↓ plasma urea, ↑ alveolitis, ↓ urine protein, ↑ prothrombin time, absent pinna reflex, ↓ abs kidney wt (♀)

Neurotoxicity Studies: Lambda-Cyhalothrin or Cyhalothrin	
Study/Species	**Results/Effects**
Acute Oral Neurotoxicity – Gavage (Lambda-Cyhalothrin in corn oil) Non-Guideline Motor Activity Long-Evans Rat PMRA# 2007554	**$BMDL_{20}$ = 0.19 mg/kg bw (♂)**, based on ↓ mean total motor activity (BMD_{20} = 0.74 mg/kg bw)
Acute Oral Neurotoxicity – Gavage (Lambda-Cyhalothrin in corn oil) Sprague-Dawley Rat PMRA# 2007556, 2043579	**NOAEL not established** **LOAEL = 10 mg/kg bw (♂)**, based on ↓ bw, salivation, lacrimation, abnormal posture, clonic convulsions, tremors, fur wetness/staining, abnormal gait, stereotypic behavior, ↓ hindlimb grip strength, ↓ hindlimb footsplay, ataxia (♂) **20 mg/kg bw (♂):** ↑ biting, ↑ splayed hindlimbs, low arousal, hindlimb weakness, ↓ forelimb grip strength, ↓ startle response, ↓ touch response, ↓ approach response, ↓ olfactory orientation, ↓ hindlimb extension, ↓ air righting reflex, ↓ rotarod performance, ↓ mean body temperature (♂)
Acute Oral Neurotoxicity – Gavage	**NOAEL = 2.5 mg/kg bw (♂/♀)**

(Lambda-Cyhalothrin in corn oil) Alpk Wistar Rat PMRA# 1124601	**LOAEL = 10 mg/kg bw (♂/♀)**, based on ↑ breathing rate, ↓ splay reflex, piloerection, urinary incontinence; salivation, upward curvature of the spine (♀) **35 mg/kg bw (♂/♀):** ↓ fc, clinical signs on day 1 (ungroomed appearance, ↓ total activity, ↓ motor activity, ataxia, reduced stability, tiptoe gait, tremors); slight transient ↓ bw, salivation, ↓ landing foot splay, ↓ hindlimb grip strength, upward curvature of the spine (♂); tremors, tail flick, minimal pigmentation in the olfactory bulb of the brain, minimal degeneration of sciatic nerve (♀)
7-Day Oral Neurotoxicity – Gavage (Cyhalothrin in distilled water) Wistar Rat PMRA# 2418363	**NOAEL = 1 mg/kg bw/day (♂)** **LOAEL = 3 mg/kg bw (♂)**, based on ↓ rearing frequency, ↑ immobility time, ↓ social interaction, ↓ locomotor activity, ↓ time spent in plus maze open-arm exploration, ↑ time spent in plus maze closed-arm exploration, ↑ serum corticosterone levels (♂) **7 mg/kg bw/day (♂):** salivation, tremors, liquid feces, chewing, head bobbing (♂)
13-Week Oral Neurotoxicity – Diet (Lambda-Cyhalothrin dissolved in corn oil) Alpk Wistar Rat PMRA# 1124599	**NOAEL = 4.6 mg/kg bw/day (♂); >12.5 mg/kg bw/day (♀)** **LOAEL = 11.4 mg/kg bw/day (♂)**, based on ↓ fc; ↓ bw, ↓ bwg (♂)
Developmental Neurotoxicity – Gavage (Lambda-Cyhalothrin dissolved in corn oil) Alpk Wistar Rat PMRA# 2235664	**Supplemental (range-finding study)** **<u>Maternal Toxicity</u>** **≥4 mg/kg bw/day (♀):** ↓ bw, ↓ fc, clinical signs (ataxia, ↓ limb function, piloerection, salivation, urinary staining, staining around mouth and nose); some dams were sacrificed due to severe clinical signs and/or parturition difficulty **8 mg/kg bw/day (♀):** mortality, bw loss, ↓ bwg **12/15 mg/kg bw/day (♀):** dams sacrificed due to severe clinical signs on day 1 **<u>Offspring Toxicity:</u>** **≥4 mg/kg bw/day (♂/♀):** ↑ pup mortality, ↑ total litter loss
Developmental Neurotoxicity – Diet (Lambda-Cyhalothrin dissolved in corn oil) Alpk Wistar Rat PMRA# 2235665	**Supplemental (range-finding study)** **<u>Maternal Toxicity</u>** **≥4.9 mg/kg bw/day (♀):** ↓ fc on GD 7 **11.4 mg/kg bw/day (♀):** ↓ bw throughout gestation due primarily to bw loss on first day of dosing, ↓ fc throughout gestation **<u>Offspring Toxicity:</u>** **≥2.1 mg/kg bw/day (♂/♀):** non-dose related ↓ pup survival PND 1 to PND 5, non-

	dose related ↑ number of missing/presumed dead pups from PND 5 to PND 8 **11.4 mg/kg bw/day (♂/♀):** ↓ pup bw PND 1 Lambda-cyhalothrin was detected in the plasma of dams and pups throughout lactation. Plasma levels of lambda-cyhalothrin in pups were generally equivalent to dams. Concentrations of lambda-cyhalothrin in the plasma of dams and pups increased with increasing dietary concentration.
Developmental Neurotoxicity – Diet (Lambda-Cyhalothrin) Non-Guideline Alpk Wistar Rat PMRA# 2127970, 2449300	**<u>Maternal Toxicity</u>** **NOAEL = 4.9 mg/kg bw/day (♀)** **LOAEL = 11.4 mg/kg bw/day (♀)**, based on ↓ bw **<u>Offspring Toxicity:</u>** **NOAEL = 4.9 mg/kg bw/day (♂/♀)** **LOAEL = 11.4 mg/kg bw/day (♂/♀),** based on ↓ pup survival PND 1 to PND 5, ↓ pup bw and bwg PND 5 to PND 29, ↑ number of pups missing, presumed dead or found dead, ↓ litter wt PND 5, ↓ brain morphometric measurements in PND12 ♂ (↓ overall width of hippocampus, ↓ thickness of molecular layer of preculminate fissure of cerebellum) and PND 63 ♂ (↓ thickness of level 3 piriform cortex), ↓ brain morphometric measurements in PND 12 ♀ (↓ thickness of level 5 dorsal cortex, ↓ thickness of level 4 dorsal cortex, ↓ width of thalamus, ↓ width of thalamus/cortex); ↑ age at preputial separation (♂); ↓ swim performance on PND 21 (learning phase), ↓ auditory startle response at PND 61 (♀) **Evidence of developmental neurotoxicity in the presence of maternal toxicity**
Delayed Neurotoxicity – Gavage (Cyhalothrin in corn oil) Domestic Hen PMRA# 1248958	**5000 mg/kg bw (♀):** ↓ bw, macroscopic changes in ovary (firm mass and prominent surface vascularization on oviduct, oviduct nodules, ovaries underdeveloped) **10,000 mg/kg bw (♀):** mortality, macroscopic changes in ovary (cystic oviduct, oviduct distended with fluid, ovaries underdeveloped) **No evidence of delayed neurotoxicity**

Chronic Toxicity/Carcinogenicity Studies: Cyhalothrin	
Study/Species	**Results/Effects**
2-Year Chronic Toxicity/Carcinogenicity – Diet (Cyhalothrin) Charles River CD-1 Mouse PMRA# 1248925, 1248926	**NOAEL = 2 mg/kg bw/day (♂/♀)** **LOAEL = 9.2/10.6 mg/kg bw/day (♂/♀),** based on ↑ AST; piloerection, hunched posture, aggressive behavior (♂); ↑ ALT, ↓ plasma cholesterol (♀) **53.2/50.7 mg/kg bw/day (♂/♀):** ↓ plasma glucose; marginal ↑ mortality, emaciation, ↓ bw, ↓ bwg, ↓ food efficiency, ↑ fc, ↓ total plasma protein and globulin, ↓ WBC count, ↓ packed cell volume, pallor, hyperactivity, ↓ abs testes wt (♂); piloerection, hunched posture, ↓ urinary protein (♀) There was an increased incidence of mammary adenocarcinoma in ♀. The incidence in ♀ (decedents and terminal sacrifice) receiving 0, 2, 10.6 or 50.7 mg/kg bw/day was 1/52 (2%), 0/52 (0%), 7/52 (14%, p=0.03) or 6/52 (12%, p=0.05); supported by positive test for trend (p=0.017). Interim treated and control animals had zero incidence of mammary adenocarcinoma. Incidence of mammary adenocarcinoma at 10.6 or 50.7 mg/kg bw/day exceeded the historical control mean of 7% (range = 1.8% to 12%). There was an increase in the combined incidence of uterine leiomyoma and leiomyosarcoma in ♀. The combined incidence in ♀ (decedents and terminal sacrifice) receiving 0, 2, 10.6 or 50.7 mg/kg bw/day was 1/52 (2%), 0/52 (0%), 3/52 (6%) or 5/52 (10%), respectively. Positive test for trend (p<0.01). Uterine leiomyoma or leiomyosarcoma were not observed in interim treated or control animals. The combined incidence of uterine leiomyoma and leiomyosarcoma at 10.6 or 50.7 mg/kg bw/day exceeded the historical control mean for "uterine smooth muscle tumors" of 3.5% (range = 0% to 10%) **Evidence of carcinogenicity**
2-Year Chronic Toxicity/Carcinogenicity Study - Diet (Cyhalothrin) Alpk:AP Wistar Rat PMRA# 1248890, 1248917, 1248921	**NOAEL = 2.5 mg/kg bw/day (♂/♀)** **LOAEL = 12.5 mg/kg bw/day (♂/♀),** based on ↓ bw, ↓ fc, stained coat, ↓ plasma triglycerides, sporadic ↓ plasma glucose, ↓ urine volume, ↑ urine specific gravity, ↑ rel liver wt; ↓ plasma cholesterol, aggressive behavior, piloerection, ↓ abs testes wt, scaly tail, ↓ spleen wt, ↓ Hgb (interim), "ballooning degeneration" of liver, ↑ incidence of tubular degeneration and calcification of testes in animals killed terminally (♂); ↑ response to touch, ↓ total protein, ↑ secretory activity of mammary gland in animals killed at termination (♀) There was an increased incidence of mammary fibroadenoma in ♀. The incidence (decedents and terminal sacrifice) at 0, 0.5, 2.5 or 12.5 mg/kg bw/day was 5/62 (8%), 4/63 (6%), 6/60 (10%) or 9/63 (14%), respectively. Positive trend test, p=0.05. Historical control data were not provided by the study authors. **Equivocal evidence of carcinogenicity**

Developmental/Reproductive Toxicity Studies	
Study/Species	**Results/Effects**
3-Generation Reproductive Toxicity Study – Diet (Cyhalothrin) Alpk Wistar Rat PMRA# 2127969, 1248955, 2448121	**Parental Toxicity** **NOAEL = 0.5 mg/kg bw/day (♀)** **LOAEL = 1.5 mg/kg bw/day (♀)**, based on ↓ bw in F_1 ♀ **NOAEL = 1.5 mg/kg bw/day (♂)** **LOAEL = 5.2 mg/kg bw/day (♂)**, based on ↓ fc (all generations); ↓ bw and bwg in F_1 ♂ and F_2 ♂; ↓ bw in F_2 ♀ **Offspring Toxicity** **NOAEL = not established** **LOAEL = 0.5 mg/kg bw/day (♂)**, based on ↓ pup bw on PND 11 in F_{3a} ♂ **≥1.5 mg/kg bw/day (♂/♀):** ↓ pup bw in F_{1b} and F_{3b}; ↓ pup bw in F_{3a} ♀ **Reproductive Toxicity** **NOAEL≥ 5.2 mg/kg bw/day (♂/♀)** Pups were likely exposed to cyhalothrin during the lactation phase, based on studies which demonstrate distribution of lambda-cyhalothrin to maternal milk in mammals (PMRA# 2235675) and humans (PMRA# 2418357, 2418359, 2418366). **Evidence of sensitivity of the young**
Developmental Toxicity – Gavage (Cyhalothrin in corn oil) CD Rat PMRA# 1248972	**Maternal Toxicity:** **NOAEL = 10 mg/kg bw/day** **LOAEL = 15 mg/kg bw/day**, based on ↓ bw, ↓ bwg, ↓ fc, loss of limb coordination **Developmental Toxicity:** **NOAEL≥ 15 mg/kg bw/day (♂/♀)** **No evidence of developmental toxicity or sensitivity of the young**
Developmental Toxicity – Gavage (Cyhalothrin in corn oil) New Zealand White Rabbit PMRA# 1248973	**Maternal Toxicity:** **NOAEL = 10 mg/kg bw/day** **LOAEL = 30 mg/kg bw/day,** based on ↓ fc, initial bw loss, ↓ bwg, head rocking side to side, agitation and resistance to handling, ovarian cysts, fallopian tubes distended with fluid **Developmental Toxicity:** **NOAEL≥ 30 mg/kg bw/day (♂/♀)** **No evidence of developmental toxicity or sensitivity of the young**

In-Vitro Genotoxicity Studies	
Study/Species	**Results/Effects**
Reverse Mutation (Lambda-Cyhalothrin in DMSO) *Salmonella typhimurium*, TA1535, TA1537, TA1538, TA98, TA100 PMRA# 1248975	Negative with or without metabolic activation Insoluble ≥ 1000 µg/mL
Reverse Mutation (Cyhalothrin in DMSO) *Salmonella typhimurium*, TA1535, TA1537, TA1538, TA98, TA100 PMRA# 1248974	Negative without metabolic activation (all strains). Negative with metabolic activation (TA1537, TA1538, TA98, TA100); TA1535 results were compromised by lack of response with positive control. Insoluble ≥2500 µg/plate
Forward Mutation (Lambda-Cyhalothrin in DMSO) L5178Y TK$^{+/-}$ Mouse Lymphoma Cells PMRA# 2235656	Negative with or without metabolic activation Insoluble ≥1000 µg/mL
Chromosomal Aberrations (Lambda-Cyhalothrin in DMSO) Human Lymphocytes Healthy Volunteers PMRA# 1248957	**Supplemental** Negative with or without metabolic activation. Insoluble at 1000 µg/mL
DNA Damage – Comet Assay (Lambda-Cyhalothrin in ethanol) BALB/c Mouse RAW 264.7 Macrophage PMRA# 2413382	**≥10^{-7} mol/L:** concentration-related ↑ DNA damage (↑ tail length, ↓ integrity of nucleolus), ↑ reactive oxygen species **$5x10^{-7}$ mol/L:** ↑ reactive oxygen species **Positive for induction of DNA damage and reactive oxygen species in mouse macrophage**
Chromosomal Aberrations and DNA Damage – Comet Assay (Lambda-Cyhalothrin in DMSO) Human Lymphocytes	**Supplemental** **≥2.2 µM**: concentration-related ↑ chromosomal aberrations (gaps, satellite associations) and ↑ DNA damage (single-strand breaks, ↑ tail length) **2.8 µM:** ↑ aneuploid cells

Healthy Volunteers PMRA# 2413378	LC_{50} = 28 µM **Positive for induction of chromosomal aberrations, DNA damage and aneuploidy in human lymphocytes**
Unscheduled DNA Synthesis (Lambda-Cyhalothrin in DMSO) HeLa Cells PMRA# 1204025	Negative with and without metabolic activation
Unscheduled DNA Synthesis (Lambda-Cyhalothrin in DMSO) Alpk Wistar Rat Hepatocytes PMRA# 2235657	Negative without metabolic activation. Insoluble $\geq 10^{-3}$ M Cytotoxic $\geq 10^{-4}$ M
Cell Transformation (Cyhalothrin in DMSO) (Non-Guideline) BHK21 C13 Neonatal Hamster Kidney Cells PMRA# 1248976	**Supplemental** **Without Activation:** **≥500 µg/mL:** ↑ cell transformation (poor dose-response) **With Activation:** Negative. Positive controls did not meet the criteria for a positive response; data were considered unacceptable **Positive for induction of cell transformation in hamster kidney cells**

In-Vivo Genotoxicity Studies	
Study/Species	**Results/Effects**
Dominant Lethal Mutation – Gavage (Cyhalothrin in corn oil) CD-1 Mouse PMRA# 1248978	Negative
Chromosomal Aberrations, Germ Cell Abnormalities – Gavage (5% Formulated Lambda-Cyhalothrin)	**Supplemental** **≥2 mg a.i./kg bw/day (♂):** dose- and time-dependent ↑ numerical and structural chromosomal aberrations in bone marrow and spermatocytes after 2 or 4 months

Swiss Mouse Bone Marrow Cells Spermatocytes PMRA# 2413365	**5 mg a.i./kg bw/day (♂):** ↑ mean number of morphologically abnormal sperm (amorphous, without hook, head and tail abnormalities), ↓ mean spermatocyte count **Positive for induction of germ cell abnormalities and chromosomal aberrations in mouse bone marrow and spermatocytes**
Micronuclei – I.P. Injection (Lambda-Cyhalothrin in corn oil) C57BL/6J Mouse Erythrocytes Bone Marrow Cells PMRA#1248956	**Supplemental** Negative in bone marrow and erythrocytes
DNA Damage – Gavage (Lambda-Cyhalothrin) Norway Rat Hepatocytes PMRA# 2413376	**0.6 mg/kg bw/day (♂):** ↑ DNA fragmentation, ↑ ALT, ↑ AST, ↑ hepatic lipid peroxidation, ↓ glutathione content, ↓ glutathione peroxidase activity, ↓ glutathione-s-transferase activity, ↓ glutathione reductase activity **Positive for induction of DNA damage and oxidative stress in rat hepatocytes**
Chromosomal Aberrations – Gavage (Cyhalothrin in corn oil) Wistar Rat Bone Marrow PMRA# 1248977	Negative
Chromosomal Aberrations – Acute or Repeated Exposure – Gavage (Lambda-Cyhalothrin in peanut oil) Albino Norway Rat Lymphocytes PMRA# 2413380, 2413381	**<u>Acute Exposure:</u>** **18 mg/kg bw (♂/♀):** slight ↑ chromatid gaps and chromosome fragments (with gaps) after 1 day, ↑ chromosome fragments (with or without gaps) after 2 days; questionable biological significance **<u>Repeated Exposure:</u>** **0.6 mg/kg bw/day (♂/♀):** ↑ frequency of aberrant cells and ↑ chromosome fragments without gaps after 30 days, ↑ DNA degradation after 15 or 30 days **Positive for induction of structural chromosomal aberrations and DNA damage in rat lymphocytes**
Micronuclei, Chromosomal Aberrations – Gavage (2.5% Formulated Lambda-Cyhalothrin in isotonic saline)	**Supplemental** **≥0.02 mg a.i./kg bw/day:** dose-related ↑ micronuclei in bone marrow, dose-related ↓ PCE:NCE in bone marrow, dose-related ↑ micronuclei in gut epithelial cells, dose-related ↑ nuclear changes (fragmentation, dissolution, binucleated cells) and ↓ mitotic index in gut epithelial cells

Wistar Rat Bone Marrow Cells Colonic Crypt Epithelial Cells PMRA# 2413367	Colonic epithelium was more sensitive to clastogenic effects, compared to bone marrow, based on the higher frequency of micronuclei and nuclear changes/damage.
Micronuclei, Chromosomal Aberrations – Gavage (2.5% Formulated Lambda-Cyhalothrin in isotonic saline) Wistar Rat Bone Marrow Cells PMRA# 2413372	**Supplemental** **≥0.02 mg a.i./kg bw/day:** dose-related ↑ chromatid and isochromatid breaks, double minute exchange, dicentric chromosomes and fragments, dose-related ↑ micronuclei, dose-related ↓ PCE:NCE
Chromosomal Aberrations, Micronuclei – I.P. Injection (2.5% Formulated Lambda-Cyhalothrin in isotonic saline) Wistar Rat Bone Marrow Cells PMRA# 2413369	**Supplemental** **≥0.02 mg a.i./kg bw/day:** dose-related ↑ structural chromosomal aberrations (primarily chromatid gaps and breaks), ↑ micronuclei and ↓ PCE:NCE

Special Studies - Non-Guideline	
Study/Species	**Results/Effects**
Developmental Toxicity – Dermal (Cyhalothrin in distilled water): 0.018% w/v aqueous cyhalothrin (1 mL) daily from GD 0 to GD 21. Wistar Rat Specialized study of reproductive and selected FOB effects PMRA# 2418360	**Supplemental** **Maternal Toxicity:** No signs of maternal toxicity. **Offspring Toxicity:** Delayed ear opening, eye opening and fur development; delayed age of testes decent (26.5 days vs 23 days for controls), ↓ number of head-dips (♂) **Evidence of developmental toxicity in the absence of maternal toxicity**
Developmental Toxicity – Dermal (Cyhalothrin in distilled water): 0.02% w/v aqueous cyhalothrin (1 mL applied to shaved backs) daily from GD 0 to GD 21	**Supplemental** **Maternal Toxicity:** No signs of maternal toxicity.

Wistar Rat Specialized study of selected reproductive effects. PMRA# 2418361	**Offspring Toxicity:** Delayed age of testes descent (26.5 days vs 23 days for controls) (♂) **Evidence of developmental toxicity in the absence of maternal toxicity**
Short-Term (6-Week) Oral Male Reproductive Toxicity – Gavage (2.5% Formulated Lambda-Cyhalothrin in corn oil) ♂ Adult CD-1 Mouse PMRA# 2413361	**Supplemental** **≥0.2 mg a.i./kg bw/day (♂):** dose-related ↑ spleen wt, ↓ testes wt, ↓ seminal vesicle wt, dose-related ↑ total number of abnormal sperm and sperm with flagellar abnormalities, histopathology in seminiferous tubules (↓ number and disruption of germ cell layers, luminal widening), ↓ number of spermatozoa, hepatic vascular congestion and hepatocyte degeneration, renal glomerular atrophy and tubular dilation, splenic effects (localized hemorrhage and megakaryocytes in red pulp) **≥0.4 mg a.i./kg bw/day (♂):** ↓ sperm motility, ↓ sperm viability, ↑ sperm with cytoplasmic droplets, histopathology in seminiferous tubules (structural disorganization of germinal epithelium, intercellular vacuolization, blood vessel congestion) and Leydig cells (degeneration), liver histopathology (dilation and congestion of portal vein, vascular degeneration, mononuclear cell infiltration), kidney effects (massive congestion in blood vessels, degeneration of epithelial cells, interstitial inflammatory cell infiltrates), splenic hemorrhage and degeneration **0.8 mg a.i./kg bw/day (♂):** ↓ kidney wt , ↓ sperm count, ↑ sperm with principal piece abnormalities, ↑ sperm head abnormalities, histopathology in seminiferous tubules (degeneration of interstitial tissue, edematous fluid, tubular atrophy, spermatogenic arrest, absence of mature spermatozoa in tubular lumen), liver effects (degeneration and "wide necrotic areas"), kidney effects (severe intertubular hemorrhage and degeneration of endothelial cells), splenic necrosis
Short-Term (28-Day) Oral Male Reproductive Toxicity – Drinking Water (5% Formulated Lambda-Cyhalothrin) ♂ Adult Wistar Rat PMRA# 2413360	**Supplemental** **61.2 mg a.i./kg bw/day (♂):** ↓ bw, ↓ abs testes wt, ↓ abs epididymis wt, ↓ abs seminal vesicle wt, ↓ sperm viability, ↓ sperm motility, ↓ sperm count, ↑ abnormal sperm morphology, ↑ testicular lipid peroxidation, ↓ reduced glutathione levels, ↓ catalase, ↓ superoxide dismutase, ↓ glutathione peroxidase, ↓ glutathione transferase, histopathological changes in the testes (irregular seminiferous tubules containing only serotoli cells, intertubular hemorrhage, pyknotic nucleus). Co-administration of quercetin with lambda-cyhalothrin significantly offset the effects on functional sperm parameters (motility, viability, count), testicular lipid peroxidation, enzymatic antioxidant activities and histopathological effects, compared to rats treated with lambda-cyhalothrin alone.
16-Week Short-Term Oral Male Reproductive Toxicity – Gavage (with or without Vitamin E in drinking water every other day) (Lambda-Cyhalothrin) ♂ Adult New Zealand White Rabbit	**20 mg/kg bw/day (♂):** ↓ fc, ↓ bw, ↓ rel testes wt, ↓ rel epididymis wt, ↓ plasma testosterone, ↓ semen volume, ↑ dead sperm, ↑ semen lipid peroxidation, ↓ semen glutathione transferase, ↓ semen AST, ALT and acid phosphatase activities, ↑ semen pH, ↓ sperm parameters (packed sperm volume, sperm concentration, total output, motility, total functional sperm fraction, number of normal sperm, fructose concentration), ↓ libido Co-administration of Vitamin E with lambda-cyhalothrin significantly suppressed the adverse morphological and functional effects on sperm quality, semen quality,

PMRA# 2418364	testosterone levels, semen lipid peroxidation levels and enzyme activities, compared to rats treated with lambda-cyhalothrin alone.
Short-Term Oral Thyroid Function – Gavage (10% Formulated Lambda-Cyhalothrin in saline) Pregnant Wistar Rat PMRA# 2448125	**Supplemental** **Maternal Toxicity:** **8 mg a.i./kg bw/day (♀):** ↓ T4 and ↓ T3 throughout gestation and lactation, ↑ TSH throughout gestation and lactation **Offspring Toxicity:** **8 mg a.i./kg bw/day (♂/♀):** delayed eye opening, delayed ear detachment, ↓ T4 and ↓ T3 (PND 7 to PND 30), ↑ TSH (PND7 to PND 30)
In Vitro Thyroid Receptor Binding Activity and Antagonistic Activity (Cyhalothrin or 3-PBA in DMSO) Receptor Mediated Reporter Gene Assay (Luciferase) CV-1 Cells PMRA# 2448124	Cyhalothrin and 3-PBA induced thyroid receptor binding antagonistic activity.
In Vitro Androgenic and Anti-Androgenic Activity (Cyhalothrin or 3-PBA in DMSO) Receptor-Mediated Reporter Gene Assay (Luciferase) MDA-kb2 Cells PMRA# 2448124	Cyhalothrin and 3-PBA induced anti-androgenic activity. No evidence of androgenic activity with cyhalothrin or 3-PBA.
In Vitro Estrogenic and Anti-Estrogenic Activity (Cyhalothrin or 3-PBA in DMSO) Receptor-Mediated Reporter Gene Assay (Luciferase) CV-1 Cells	Cyhalothrin demonstrated weak estrogenic activity in vitro. 3-PBA demonstrated anti-estrogenic activity in vitro.

PMRA# 2448124	
In Vitro Estrogenic Activity (Lambda-Cyhalothrin) MCF-7 Human Breast Carcinoma Cells PMRA# 2448126	Positive for estrogenic activity in vitro, based on concentration-related ↑ cell proliferation, ↑ Trefoil factor (pS2) mRNA, ↑ progesterone receptor mRNA, ↓ ERα and ERβ protein and mRNA. The treatment-related ↑ cell proliferation and ↑ pS2 gene expression were completely inhibited with estrogen-receptor agonist (ICI 182,780).
Short-Term Oral (21-Day) Oxidative Stress Assay - Drinking Water (with i.p. injection of either saline or 200 mg/kg bw/day Vitamin C) (5% Formulated Lambda-Cyhalothrin in saline) Wistar Rat PMRA# 2448122, 2448123, 2448127	**Supplemental** **668 ppm (♂):** ↓ wc, ↓ fc, ↓ bw, ↓ liver wt, ↑ lactate dehydrogenase, ↑ AST, ↑ ALT, ↑ plasma urea, ↑ creatinine, ↑ BUN, ↑ lipid peroxidation in all tissues, ↓ antioxidant enzyme activities in all tissues (superoxide dismutase, catalase, glutathione peroxidase, glutathione reductase, glutathione transferase), ↓ GSH content in all tissues, ↓ RBC, ↓ Hgb, ↓ Hct, ↓ platelet count, liver histopathology (necrosis, marked leukocyte infiltration), kidney histopathology (desquamation, inflammatory cell infiltration, tubular dilation and swelling) Co-treatment with lambda-cyhalothrin and 200 mg/kg bw/day Vitamin C resulted in ↓ severity (or reversal) of effects on all parameters including histopathology, compared to animals receiving lambda-cyhalothrin alone.

Appendix IV Dietary Exposure and Risk Estimates for Lambda-Cyhalothrin

Table 1 Summary of Dietary (Food and Drinking Water) Exposure and Risk from Lambda-Cyhalothrin

Subpopulation	Acute Dietary 99.9th Percentile		Chronic Dietary		Cancer Dietary	
	Dietary Exposure (mg/kg bw)	%ARfD[1]	Dietary Exposure (mg/kg bw/day)	%ADI[2]	Dietary Exposure (mg/kg bw/day)	Lifetime cancer risk[3]
General Population	0.004758	793	0.000201	67	0.000201	5E-06
All Infants (<1 year old)	0.005344	891	0.000152	51	N/A	
Children 1-2 years old	0.003969	661	0.000344	115		
Children 3-5 years old	0.003195	533	0.000246	82		
Children 6-12 years old	0.002182	364	0.000150	50		
Youth 13-19 years old	0.005180	863	0.000120	40		
Adults 20-49 years old	0.005479	913	0.000249	83		
Adults 50-99 years old	0.004109	685	0.000160	53		
Female 13-49 years old	0.003867	644	0.000141	47		

[1] Acute Reference Dose (ARfD) of 0.0006 mg/kg bw.
[2] Acceptable Daily Intake (ADI) of 0.0003 mg/kg bw/day.
[3] q_1^* of 0.0266 (mg/kg bw/day)$^{-1}$.
N/A = not applicable.
Shaded cells indicate risks of concern.

Appendix V Food Residue Chemistry Summary

Lambda-cyhalothrin is an insecticide registered for use on a variety of food crops including apples, asparagus, bulb vegetables, celery, cereal grains, cherries, cucurbit vegetables, flax, fruiting vegetables, head and stem *Brassica*, kohlrabi, leafy vegetables, legume vegetables, mustard, nectarines, oilseeds, peaches, pears, plums, rapeseed (canola), root and tuber vegetables, Saskatoon berries, strawberries, and tree nuts, as well as on greenhouse lettuce. It is also registered for use on feed crops such as alfalfa, timothy, unimproved pasture and summerfallow, and may be applied as a direct treatment to cattle (ear tag and pour-on products). Since the product may be applied as a structural treatment in food-handling establishments, an MRL of 0.01 ppm has been established for all food commodities (other than those already covered by a higher MRL as a result of use on growing crops) in food-handling establishments where food products are held, processed or prepared.

The nature of the residue in plant and animal commodities is adequately understood based on acceptable metabolism studies in goat, cattle, hens, apples, cabbage, cotton, soybean and wheat. The residue definition in plant and animal commodities is lambda-cyhalothrin (stereoisomers 1R,cis,Z-S' and 1S,cis,Z-R') and its epimer (stereoisomers 1R,cis,Z-R' and 1S,cis,Z-S'). This residue definition also encompasses cyhalothrin (the sum of the four stereoisomers), and gamma-cyhalothrin (stereoisomer 1R,cis,Z-S' only). Cyhalothrin is a historical active ingredient with no current registrations, and gamma-cyhalothrin is currently registered in the United States but not in Canada. Lambda-cyhalothrin is registered for use in many countries, including Canada and the US.

Lambda-cyhalothrin shares some common metabolites (for example, 3-phenoxybenzoic acid and 3-phenoxybenzoic alcohol) with other pyrethroid active ingredients such as permethrin. These metabolites are not considered residues of concern for lambda-cyhalothrin and will be taken into consideration during the cumulative risk assessment of pyrethroids.

Numerous analytical methods have been previously reviewed and deemed acceptable for data collection, enforcement and multi-residue analysis. Quantitation of the residues of lambda-cyhalothrin and its epimer is performed by gas chromatography (GC) or gas-liquid chromatography (GLC) coupled with an electron capture detector (ECD) or a mass selective detector (MSD). Lambda-cyhalothrin's epimer is not analyzed for in some of the accepted analytical methods; however, these were previously reviewed by the PMRA and deemed acceptable based on the fact that the epimer accounts for only approximately 10% of lambda-cyhalothrin residues.

The current enforcement methods for plant and animal commodities do not distinguish between lambda- and gamma-cyhalothrin. If food uses had been maintained as a result of this re-evaluation, methods to differentiate lambda-cyhalothrin from gamma-cyhalothrin in plant and animal commodities would have been required.

Although there are a large number of crops which do not have data specifically meeting the geographic requirements specified by the PMRA's "Residue Chemistry Guidelines" (DIR98-02 and DIR2010-05) and a small number of crops which do not have the total required number of trials, the data submitted to PMRA were previously reviewed and deemed adequate to support their current use patterns.

Overall, sufficient information was available to adequately assess the acute, chronic and cancer dietary risks from exposure to lambda-cyhalothrin.

Appendix VI Supplemental Maximum Residue Limit (MRL) Information – International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For animal commodities, differences in MRLs can be due to different livestock feed items and practices. There are MRLs or tolerances specified for lambda-cyhalothrin in Canada, the United States, and by CODEX Alimentarius. The MRLs and tolerances can be found in Table 1.

The MRLs specified for lambda-cyhalothrin in Canada are proposed to be revoked as a result of the re-evaluation. Due to potential trade implications, the PMRA will consult with all interested stakeholders before making a final decision on the revocation of Canadian MRLs.

Table 1 Canadian MRLs and International Tolerances/MRLs for Lambda-Cyhalothrin as of June 2015

NOTE: American Tolerances for gamma-cyhalothrin are presented for information/comparison purposes only.

Commodity	Canadian MRL[a] (ppm)	United States Tolerance (ppm)		Codex MRL (ppm)
		Lambda	Gamma	
African eggplants	0.2	0.20	0.20	-
African tree nuts	0.05	0.05	0.05	-
Alfalfa, forage	-	5.0	5.0	-
Alfalfa, hay	-	6.0	6.0	-
Almond nuts	0.05	0.05	0.05	0.01
Almond, hulls	-	1.5	1.5	2
American plums	0.5	0.50	0.50	0.2
Apples	0.3	0.30	0.30	0.2
Apple, wet pomace	-	2.50	2.50	-
Apricots	0.5	0.50	0.50	0.5
Arracacha	0.02	0.02	-	0.01
Arrowroot	0.02	0.02	-	0.01
Asian pears	0.3	0.30	0.30	-
Asparagus	0.02	-	-	0.02
Avocados	0.2	0.20	0.20	-
Azaroles	0.3	0.30	0.30	-
Balsam apples	0.05	0.05	-	0.05
Balsam pears	0.05	0.05	-	0.05
Barley	0.05	0.05	-	0.5
Barley bran	0.2	0.2	-	-
Barley, hay	-	2.0	-	-
Barley, straw	-	2.0	-	2
Beach plums	0.5	0.50	0.50	-
Beechnuts	0.05	0.05	0.05	0.01
Bell peppers	0.2	0.20	0.20	0.3

Commodity	Canadian MRL[a] (ppm)	United States Tolerance (ppm)		Codex MRL (ppm)
		Lambda	Gamma	
Black cherries	0.5	0.50	0.50	0.3
Black walnuts	0.05	0.05	0.05	0.01
Brazil nuts	0.05	0.05	0.05	0.01
Brazilian pine nuts	0.05	0.05	0.05	-
Broccoli	0.4	0.4	0.4	0.5
Brussels sprouts	0.4	0.4	0.4	-
Buckwheat	0.05	0.05	-	-
Bunya nuts	0.05	0.05	0.05	-
Bur oak nuts	0.05	0.05	0.05	-
Bush tomatoes	0.2	0.20	0.20	-
Butternuts	0.05	0.05	0.05	0.01
Cabbages	0.4	0.4	0.4	0.3
Cajou nuts	0.05	0.05	0.05	-
Canada plums	0.5	0.50	0.50	-
Candlenuts	0.05	0.05	0.05	-
Canola oil	0.5	2.0	-	-
Cantaloupes	0.05	0.05	-	0.05
Capulins	0.5	0.50	0.50	-
Cardoon	0.3	-	-	-
Carrot roots	0.01	-	-	0.01
Cashew nuts	0.05	0.05	0.05	0.01
Cassava roots	0.02	0.02	-	0.01
Cauliflowers	0.4	0.4	0.4	0.5
Celery	0.3	-	-	-
Celtuce	0.3	-	-	-
Chayote fruit	0.05	0.05	-	0.05
Chayote roots	0.02	0.02	-	0.01
Cherry plums	0.5	0.50	0.50	0.2
Chestnuts	0.05	0.05	0.05	0.01
Chickasaw plums	0.5	0.50	0.50	0.2
Chinese artichokes	0.02	0.02	-	-
Chinese broccoli	0.4	0.4	0.4	0.5
Chinese celery	0.3	-	-	-
Chinese cucumbers	0.05	0.05	-	-
Chinese mustard cabbages	0.4	0.4	0.4	-
Chinese onions	0.1	-	-	-
Chinese quinces	0.3	0.30	0.30	-
Chinese waxgourds	0.05	0.05	-	-
Chinquapin nuts	0.05	0.05	0.05	0.01
Chokecherries	0.5	-	-	-
Chufa	0.02	0.02	-	0.01
Citron melons	0.05	0.05	-	0.05

Commodity	Canadian MRL[a] (ppm)	United States Tolerance (ppm)		Codex MRL (ppm)
		Lambda	Gamma	
Coconas	0.2	0.20	0.20	-
Coconuts	0.05	0.05	0.05	0.01
Coquito nuts	0.05	0.05	0.05	-
Crabapples	0.3	0.30	0.30	0.2
Cucumbers	0.05	0.05	-	0.05
Currant tomatoes	0.2	0.20	0.20	-
Damson plums	0.5	0.50	0.50	0.2
Dika nuts	0.05	0.05	0.05	-
Dry adzuki beans	0.1	0.10	0.10	0.05
Dry beans	0.1	0.10	0.10	0.05
Dry blackeyed peas	0.1	0.10	0.10	-
Dry broad beans	0.1	0.10	0.10	0.05
Dry bulb onions	0.1	0.1	0.1	0.2
Dry catjang seeds	0.1	0.10	0.10	-
Dry chickpeas	0.1	0.10	0.10	0.05
Dry cowpea seeds	0.1	0.10	0.10	0.05
Dry field peas	0.1	0.10	0.10	0.05
Dry guar seeds	0.1	0.10	0.10	-
Dry kidney beans	0.1	0.10	0.10	0.05
Dry lablab beans	0.1	0.10	0.10	0.05
Dry lentils	0.1	0.10	0.10	0.05
Dry lima beans	0.1	0.10	0.10	0.05
Dry moth beans	0.1	0.10	0.10	0.05
Dry mung beans	0.1	0.10	0.10	0.05
Dry navy beans	0.1	0.10	0.10	0.05
Dry pigeon peas	0.1	0.10	0.10	0.05
Dry pink beans	0.1	0.10	0.10	-
Dry pinto beans	0.1	0.10	0.10	-
Dry rice beans	0.1	0.10	0.10	0.05
Dry southern peas	0.1	0.10	0.10	-
Dry soybeans	0.02	0.01	0.01	0.05
Dry tepary beans	0.1	0.10	0.10	0.05
Dry urd beans	0.1	0.10	0.10	0.05
Edible canna	0.02	0.02	-	0.01
Edible gourds (other than those otherwise listed)	0.05	0.05	-	-
Edible-podded dwarf peas	0.2	0.20	0.20	0.2
Edible-podded jackbeans	0.2	0.20	0.20	0.2
Edible-podded moth beans	0.2	0.20	0.20	0.2
Edible-podded peas	0.2	0.20	0.20	0.2
Edible-podded pigeon peas	0.2	0.20	0.20	0.2

Commodity	Canadian MRL[a] (ppm)	United States Tolerance (ppm)		Codex MRL (ppm)
		Lambda	Gamma	
Edible-podded runner beans	0.2	0.20	0.20	0.2
Edible-podded snap beans	0.2	0.20	0.20	0.2
Edible-podded snow peas	0.2	0.20	0.20	-
Edible-podded soybeans	0.2	0.20	0.20	0.2
Edible-podded sugar snap peas	0.2	0.20	0.20	-
Edible-podded sword beans	0.2	0.20	0.20	0.2
Edible-podded wax beans	0.2	0.20	0.20	-
Edible-podded yardlong beans	0.2	0.20	0.20	0.2
Eggplants	0.2	0.20	0.20	0.3
Eggs	0.01	0.01	0.01	-
English walnuts	0.05	0.05	0.05	0.01
Fat of cattle	5	3.0	3	3
Fat of goats	5	3.0	3.0	3
Fat of hogs	0.5	0.2	3.0	3
Fat of horses	5	3.0	3.0	3
Fat of poultry	0.01	0.03	0.03	3
Fat of sheep	5	3.0	3.0	3
Field corn	0.05	0.05	0.05	0.02 [Maize]
Field corn flour	0.15	0.15	0.15	-
Field corn forage	-	6.0	6.0	-
Field corn stover	-	1.0	1.0	-
Fresh Florence fennel leaves and stalks	0.3	-	-	-
Fresh prune plums	0.5	0.50	0.50	-
Garden huckleberries	0.2	0.20	0.20	0.2
Garlic	0.1	0.1	0.10	0.2
Ginger roots	0.02	0.02	-	0.05
Ginkgo nuts	0.05	0.05	0.05	-
Goji berries	0.2	0.20	0.20	-
Grain, aspirated fractions	-	2.0	2.0	-
Grain lupin	0.1	0.10	0.10	-
Grapes	0.2	-	-	0.2
Great headed garlic	0.1	-	-	0.2
Green onions	0.1	-	-	0.2
Groundcherries	0.2	0.20	0.20	0.3
Guiana chestnuts	0.05	0.05	0.05	-
Hazelnuts	0.05	0.05	0.05	0.01

Commodity	Canadian MRL[a] (ppm)	United States Tolerance (ppm)		Codex MRL (ppm)
		Lambda	Gamma	
Head lettuce	2	2.0	2.0	-
Heartnuts	0.05	0.05	0.05	-
Hickory nuts	0.05	0.05	0.05	0.01
Hop, dried cones	-	10.0	-	-
Japanese apricots	0.5	0.50	0.50	-
Japanese horse-chestnuts	0.05	0.05	0.05	0.01
Japanese plums	0.5	0.50	0.50	0.2
Japanese quinces	0.3	0.30	0.30	-
Jerusalem artichokes	0.02	0.02	-	0.01
Klamath plums	0.5	0.50	0.50	-
Kohlrabies	0.4	0.4	0.4	-
Leaf lettuce	2	2.0	2.0	-
Leeks	0.15	-	-	0.2
Lerens	0.02	0.02	-	0.01
Loquats	0.3	0.30	0.30	0.2
Macadamia nuts	0.05	0.05	0.05	0.01
Mango	*	-	-	0.2
Martynias	0.2	0.20	0.20	-
Mayhaws	0.3	0.30	0.30	-
Meat byproducts of cattle	0.2	0.2	0.2	0.2 [Kidney] 0.05 [Liver]
Meat byproducts of goats	0.2	0.2	0.2	0.2 [Kidney] 0.05 [Liver]
Meat byproducts of hogs	0.01	0.02	0.2	0.2 [Kidney] 0.05 [Liver]
Meat byproducts of horses	0.2	0.2	0.2	-
Meat byproducts of poultry	0.01	0.01	0.01	-
Meat byproducts of sheep	0.2	0.2	0.2	0.2 [Kidney] 0.05 [Liver]
Meat of cattle	0.2	0.2	0.2	-
Meat of goats	0.2	0.2	0.2	-
Meat of hogs	0.01	0.01	0.2	-
Meat of horses	0.2	0.2	0.2	-
Meat of poultry	0.01	0.01	0.01	-
Meat of sheep	0.2	0.2	0.2	-
Medlars	0.3	0.30	0.30	0.2
Milk	0.5	0.4**	0.2**	0.2
Milk fat	12	10.0	5.0	-
Mongongo nuts	0.05	0.05	0.05	-
Monkey puzzle nuts	0.05	0.05	0.05	-
Monkey-pot nuts	0.05	0.05	0.05	-

Commodity	Canadian MRL[a] (ppm)	United States Tolerance (ppm)		Codex MRL (ppm)
		Lambda	Gamma	
Muskmelons (other than those otherwise listed)	0.05	0.05	-	0.05
Mustard seeds	0.01	-	-	0.2
Nanking cherries	0.5	0.50	0.50	-
Napa Chinese cabbages	0.4	0.4	0.4	-
Naranjillas	0.2	0.20	0.20	0.3
Nectarines	0.5	0.50	0.50	0.5
Non-bell peppers	0.2	0.20	0.20	0.3
Oats	0.05	0.05	-	0.05
Oat, forage	-	2.0	-	2
Oat, hay	-	2.0	-	-
Oat, straw	-	2.0	-	2
Okari nuts	0.05	0.05	0.05	-
Okras	0.2	0.20	0.20	0.3
Olives	0.5	-	-	1
Oranges	0.2	-	-	0.2
Pachira nuts	0.05	0.05	0.05	0.01
Pea eggplants	0.2	0.20	0.20	-
Peach palm nuts	0.05	0.05	0.05	-
Peaches	0.5	0.50	0.50	0.5
Peanuts	0.05	0.05	0.05	0.2
Peanut, hay	-	3.0	3.0	-
Pearl millet	0.05	-	-	-
Pears	0.3	0.30	0.30	0.2
Pecan nuts	0.05	0.05	0.05	0.01
Pepinos	0.2	0.20	0.20	0.3
Peppers Chili, dried	*	-	-	3
Pequi nuts	0.05	0.05	0.05	-
Pili nuts	0.05	0.05	0.05	0.01
Pine nuts	0.05	0.05	0.05	0.01
Pistachio nuts	0.05	0.05	0.05	0.01
Plumcots	0.5	0.50	0.50	-
Plums	0.5	0.50	0.50	0.2
Popcorn grain	0.05	0.05	0.05	-
Popcorn grain flour	*	0.05	-	-
Popcorn stover	-	1.0	1.0	-
Potato onions	0.1	-	-	-
Potatoes	0.02	0.02	-	0.01
Proso millet	0.05	-	-	-
Pumpkins	0.05	0.05	-	0.05
Quinces	0.3	0.30	0.30	0.2
Rapeseeds (canola)	0.3	1.0	0.15	0.2

Commodity	Canadian MRL[a] (ppm)	United States Tolerance (ppm)		Codex MRL (ppm)
		Lambda	Gamma	
Rhubarb	0.3	-	-	-
Rice	1	1.0	1.0	1
Rice, hulls	-	5.0	5.0	-
Rice, straw	-	1.8	1.8	2
Roselles	0.2	0.20	0.20	-
Rye	0.05	0.05	-	0.05
Rye bran	0.2	0.2	-	-
Rye, forage	-	2.0	-	2
Rye, straw	-	2.0	-	2
Sapucaia nuts	0.05	0.05	0.05	0.01
Saskatoon berries (juneberries)	0.08	-	-	0.2
Satsuma mandarins	0.2	-	-	0.2
Scarlet eggplants	0.2	0.20	0.20	-
Shallots	0.1	-	-	0.2
Sloes	0.5	0.50	0.50	-
Sorghum	0.2	0.2	0.20	-
Sorghum, forage	-	0.30	0.30	-
Sorghum, stover	-	0.50	0.50	-
Strawberries	0.01	-	-	0.2
Succulent shelled English peas	0.02	0.01	0.01	-
Succulent shelled blackeyed peas	0.02	0.01	0.01	-
Succulent shelled broad beans	0.02	0.01	0.01	0.2
Succulent shelled garden peas	0.02	0.01	0.01	0.2
Succulent shelled green peas	0.02	0.01	0.01	-
Succulent shelled lima beans	0.02	0.01	0.01	0.2
Succulent shelled peas	0.02	0.01	0.01	0.2
Succulent shelled pigeon peas	0.02	0.01	0.01	0.2
Succulent shelled southern peas	0.02	0.01	0.01	-
Sugarcane cane	0.05	0.05	0.05	0.05
Summer squash	0.05	0.05	-	0.05
Sunberries	0.2	0.20	0.20	-
Sunflower oil	0.3	0.30	0.30	-
Sunflower seeds	0.2	0.2	0.20	0.2

Commodity	Canadian MRL[a] (ppm)	United States Tolerance (ppm)		Codex MRL (ppm)
		Lambda	Gamma	
Sunflower, forage	-	0.2	0.20	-
Sunflower, hulls	-	0.50	0.50	-
Sweet cherries	0.5	0.50	0.50	0.3
Sweet corn kernels plus cob with husks removed	0.05	0.05	0.05	0.3
Sweet corn forage	-	6.0	6.0	-
Sweet corn stover	-	1.0	1.0	-
Sweet potato roots	0.02	0.02	-	0.01
Swiss chard	0.3	-	-	-
Tanier corms	0.02	0.02	-	0.01
Taro corms	0.02	0.02	-	0.01
Tart cherries	0.5	0.50	0.50	0.3
Tea (dried leaves)	2	-	-	-
Tejocotes	0.3	0.30	0.30	-
Teosinte	0.05	-	-	-
Tomatillos	0.2	0.20	0.20	0.3
Tomatoes	0.2	0.1	0.10	0.3
Tomato, dry pomace	-	6.0	6.0	-
Tomato, wet pomace	-	6.0	6.0	-
Tree onion tops	0.1	-	-	0.2
Tree tomatoes	0.2	0.20	0.20	-
Triticale	0.05	-	-	0.05
Tropical almond nuts	0.05	0.05	0.05	0.01
True yam tubers	0.02	0.02	-	0.01
Turmeric roots	0.02	0.02	-	0.05
Undelinted cotton seeds	0.05	0.05	0.05	0.2
Watermelons	0.05	0.05	-	0.05
Welsh onion tops	0.1	-	-	0.2
West Indian gherkins	0.05	0.05	-	0.05
Wheat	0.05	0.05	0.05	0.05
Wheat bran	0.2	0.2	2.0	0.1
Wheat, forage	-	2.0	2.0	2
Wheat, hay	-	2.0	2.0	-
Wheat, straw	-	2.0	2.0	2
Wild rice	1	1.0	-	-
Winter squash	0.05	0.05	-	0.05
Yam bean roots	0.02	0.02	-	0.01
Yellowhorn nuts	0.05	0.05	0.05	-
Commodity groupings				
Berries and other small fruits (other)	*	-	-	0.2
Bulb vegetables (other)	*	-	-	0.2

Commodity	Canadian MRL[a] (ppm)	United States Tolerance (ppm)		Codex MRL (ppm)
		Lambda	Gamma	
Citrus fruits (other)	*	-	-	0.2
Dried grapes	*	-	-	0.3 [Dried grapes (currants, raisins and sultanas)]
Brassica (other)	*	0.4 [Brassica, head and stem, subgroup 5A]	0.4 [Brassica, head and stem, subgroup 5A]	0.5 [Flowerhead brassicas]
Fruiting vegetables other than cucurbits (other)	*	0.20 [Vegetable, fruiting, group 8]	0.20 [Vegetable, fruiting, group 8]	0.3 [Fruiting vegetables other than cucurbits]
Fruiting vegetables, Cucurbits (other)	*	0.05 [Vegetable, cucurbit, group 9]	-	0.05 [Fruiting vegetables, cucurbits]
Grass, forage, fodder and hay (other)	-	7.0 [Grass, forage, fodder and hay]	-	2 [Straw and fodder (dry) of cereal grains]
Legume vegetables (other)	*	0.20 [Vegetable, legume, edible podded, subgroup 6A] 0.01 [Pea and bean, succulent shelled, subgroup 6B] 0.10 [Pea and bean, dried shelled, except soybean, subgroup 6C]	0.20 [Vegetable, legume, edible podded, subgroup 6A] 0.01 [Pea and bean, succulent shelled, subgroup 6B] 0.10 [Pea and bean, dried shelled, except soybean, subgroup 6C]	0.2 [Legume vegetables]
Oilseed (other)	*	-	-	0.2 [Oilseed]
Pome fruits (other)	*	0.30 [Fruit, pome, group 11]	0.30 [Fruit, pome, group 11]	0.2 [Pome fruits]
Pulses (other)	*	-	-	0.05 [Pulses]

Commodity	Canadian MRL[a] (ppm)	United States Tolerance (ppm)		Codex MRL (ppm)
		Lambda	Gamma	
Root and tuber vegetables (other)	*	0.02 [Vegetables, tuberous and corm, subgroup 1C]	-	0.01 [Root and tuber vegetables]
Spices, Fruits and Berries (other)	*	-	-	0.03 [Spices, Fruits and Berries]
Spices, Roots and Rhizomes (other)	*	-	-	0.05 [Spices, Roots and Rhizomes]
Stone fruit (other)	*	0.50 [Fruit, stone, group 12]	0.50 [Fruit, stone, group 12]	-
Tree nuts (other)	*	0.05 [Nut, tree, group 14]	0.05 [Nut, tree, group 14]	0.01 [Tree nuts]
All food commodities (other than those already covered by a higher MRL as a result of use on growing crops) in food-handling establishments where food products are held, processed or prepared	0.01	-	-	-
All other crops appearing on the registered labels	*	-	-	-

* Covered under Part B, Division 15, subsection B.15.002(1) of the FDR as 0.1 ppm.
** The tolerance for milk fat is reflective of the tolerance in whole milk[b].
[a] Maximum Residue Limits for Pesticides webpage

Table 2 Residue Definition in Canada and Other Jurisdictions

Jurisdiction		Residue Definition
Canada	Current	(S)-α-cyano-3-phenoxybenzyl (Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl (Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate, including the epimer, in a 1:1 mixture, (R)-α-cyano-3-phenoxybenzyl (Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate
	Proposed	**Sum of lambda-cyhalothrin, a 1:1 mixture of** (S)-α-cyano-3-phenoxybenzyl (*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-

		dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl (*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate, **and its** epimer, a 1:1 mixture of (*R*)-α-cyano-3-phenoxybenzyl (*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3-phenoxybenzyl (*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate **expressed as lambda-cyhalothrin.**
United States		The combined residues of the pyrethroid lambda-cyhalothrin, 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer expressed as epimer of lambda-cyhalothrin, a 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate
Codex (JMPR)		Cyhalothrin (sum of all isomers)
EU		Lambda-cyhalothrin, including other mixed isomeric consituents (sum of isomers)

Appendix VII Non-Occupational Risk Assessment

Table 1 Postapplication Inhalation Exposure from Indoor Surface-Directed Sprays

Exposure Scenario	Formulation	Lifestage	Mass of a.i. (mg) [a]	Exposure Time (hour) [b]	Inhalation Exposure (mg/kg bw/day) [c]	MOE [d]
Surface-Directed Spray	Pressurized Product	Adults	600	16	9.10E-08	880000
		Youth 11<16 years	600	15	1.20E-07	690000
		Children 1 <2 years	600	18	3.90E-07	200000
	Liquid	Adults	26389	16	4.00E-06	20000
		Youth 11<16 years	26389	15	5.10E-06	16000
		Children 1 <2 years	26389	18	1.70E-05	4700

[a] Where Mass (M_{Label}) = Application Rate (0.0003 kg a.i./can or L) × Amount Used (2 cans or 150 L) × 1.00E06 mg/kg.

[b] Exposure Time (hr/day) default values obtained from the USEPA Residential SOPs (2012).

[c] Where inhalation exposure (mg/kg bw/day) = $((IR \times M) \div ACH \times V \times BW) \times [1 - ((ACH \times e^{-k \times ET}) - (k \times e^{-ACH \times ET})) \div (ACH - k)]$
The equation assumes 100% absorption through inhalation, air exchanges (ACH) = 0.45 hr^{-1}, volume of a room (V) = 33 m^3, decay rate (k) = 9.5E-06 hr^{-1}, M = mass of a.i., ET = exposure time. Inhalation rates (IR) of 0.64, 0.63 and 0.33 m^3/hr and body weights (BW) of 80, 57 and 11 kg were used for adults, youth and children (1<2 years old) respectively, as stated in the USEPA Residential SOPs (2012).

[d] MOE = margin of exposure. MOE = NOAEL ÷ Exposure, based on an inhalation NOAEL of 0.08 mg/kg bw/day and a target MOE of 300 applicable to all durations of exposure

Table 2 Postapplication Dermal Exposure from Floor and Carpets – Pressurized Product Formulation

Exposure Scenario		Lifestage	Transferable Residue [a] ($\mu g/cm^2$)	TC [b] (cm^2/hr)	ET [c] (hr/day)	Dermal Exposure [d] (mg/kg bw/day)	Dermal MOE [e] (rounded)
Band/Spot /Bedbug (Pin Stream)	Carpet	Adults	0.066	6800	8	0.0449	220
		Youth 11 <16 years	0.066	5600	5	0.0324	310
		Children 1 <2 years	0.066	1800	4	0.0432	230
	Hard surface	Adults	0.088	6800	2	0.0150	670
		Youth 11 <16 years	0.088	5600	1	0.0086	1200
		Children 1 <2 years	0.088	1800	2	0.0288	350
Crack and crevice (Non-Bedbug)	Carpet	Adults	0.018	6800	8	0.0122	820
		Youth 11 <16 years	0.018	5600	5	0.0088	1100
		Children 1 <2 years	0.018	1800	4	0.0118	850
	Hard surface	Adults	0.024	6800	2	0.0041	2500
		Youth 11 <16 years	0.024	5600	1	0.0024	4200
		Children 1 <2 years	0.024	1800	2	0.0079	1300

[a] Where Transferable Residue ($\mu g/cm^2$) = Deposited Residue ($\mu g/cm^2$) × Fraction Transferred (%). Deposited residues were defaults from the USEPA Residential SOPs (2012).

[b] Transfer Coefficient (cm^2/hr) default values obtained from the USEPA Residential SOPs (2012).

[c] Exposure Time (hr/day) default values obtained from the USEPA Residential SOPs (2012).

[d] Where Dermal Exposure (mg/kg bw/day) = (Transferable Residue ($\mu g/cm^2$) × 0.001 mg/μg × Transfer Coefficient (cm^2/hr) × Exposure Time (hr/day))/Body Weight (kg). Body weights of 80, 57 and 11 kg were used for adults, youths (11 <16 years), and children (1 <2 years) respectively, as stated in the USEPA Residential SOPs (2012).

[e] MOE = margin of exposure. MOE = NOAEL ÷ exposure, based on a dermal NOAEL of 10 mg/kg bw/day and a target MOE of 300 applicable to short- and intermediate-term scenarios. Shaded cells indicate targets not met.

Table 3 Postapplication Dermal Exposure from Floor and Carpets – Liquid Product Formulation

Exposure Scenario		Lifestage	Transferable Residue [a] (µg/cm^2)	TC [b] (cm^2/hr)	ET [c] (hr/day)	Dermal Exposure [d] (mg/kg bw/day)	Dermal MOE [e] (rounded)
Band/Spot (Pin Stream)	Carpet	Adults	0.096	6800	8	6.53E-02	150
		Youth 11 <16 years	0.096	5600	5	4.72E-02	210
		Children 1 <2 years	0.096	1800	4	6.28E-02	160
	Hard surface	Adults	0.128	6800	2	2.18E-02	460
		Youth 11 <16 years	0.128	5600	1	1.26E-02	800
		Children 1 <2 years	0.128	1800	2	4.19E-02	240
Bedbug treatment [f]	Carpet	Adults	0.048	6800	8	3.26E-02	310
		Youth 11 <16 years	0.048	5600	5	2.36E-02	420
		Children 1 <2 years	0.048	1800	4	3.14E-02	320
	Hard surface	Adults	0.064	6800	2	1.09E-02	920
		Youth 11 <16 years	0.064	5600	1	6.29E-03	1600
		Children 1 <2 years	0.064	1800	2	2.09E-02	480
Crack and Crevice	Carpet	Adults	0.0192	6800	8	1.31E-02	770
		Youth 11 <16 years	0.0192	5600	5	9.43E-03	1100
		Children 1 <2 years	0.0192	1800	4	1.26E-02	800
	Hard Surface	Adults	0.0256	6800	2	4.35E-03	2300
		Youth 11 <16 years	0.0256	5600	1	2.52E-03	4000
		Children 1 <2 years	0.0256	1800	2	8.38E-03	1200

[a] Where Transferable Residue (µg/cm^2) = Deposited Residue (µg/cm^2) × Fraction Transferred (%). Deposited residues were calculated based on maximum label application rates using the USEPA Residential SOPs (2012) algorithms for all scenarios. For band/spot applications, it is assumed that the deposited residue available is 50% of the deposited residue available from broadcast applications (100% of the application rate). It is assumed to be 25% for bedbug treatment, and 10% for crack and crevice.

[b] Transfer Coefficient (cm^2/hr) default values obtained from the USEPA Residential SOPs (2012).

[c] Exposure Time (hr/day) default values obtained from the USEPA Residential SOPs (2012).

[d] Where Dermal Exposure (mg/kg bw/day) = (Transferable Residue (µg/cm^2) × 0.001 mg/µg × Transfer Coefficient (cm^2/hr) × Exposure Time (hr/day))/Body Weight (kg). Body weights of 80, 57 and 11 kg were used for adults, youths (11 <16 years), and children (1 <2 years) respectively, as stated in the USEPA Residential SOPs (2012).

[e] MOE = margin of exposure; MOE = NOAEL ÷ exposure, based on a dermal NOAEL of 10 mg/kg bw/day and a target MOE of 300 applicable to short- and intermediate-term scenarios. Shaded cells indicate targets not met.

[f] Bedbug application is defined as pin stream surface application to limited areas as well as crack and crevice application. Therefore, the percent of deposited residue available is assumed to be 25%.

Table 4 Postapplication Dermal Exposure from Outdoor Gardens and Trees

Exposure Scenario	Lifestage	DFR_t [a] ($\mu g/cm^2$)	TC [b] (cm^2/hr)	ET [c] (hr/day)	Dermal Exposure [d] (mg/kg bw/day)	Dermal MOE [e] (rounded)
Gardens	Adults	0.115	8400	2.2	2.66E-02	380
	Youth 11 <16 years		6900	2.2	3.07E-02	330
	Children 6<11 years		4600	1.1	1.82E-02	550
Trees	Adults	0.115	1700	1	2.45E-03	4080
	Youth 11 <16 years		1400	1	2.83E-03	3530
	Children 6<11 years		930	0.5	1.67E-03	5970

[a] DFR_t was calculated based on default inputs from the USEPA Residential SOPs (2012).
[b] Transfer Coefficient (cm^2/hr) default values obtained from the USEPA Residential SOPs (2012).
[c] Exposure Time (hr/day) default values obtained from the USEPA Residential SOPs (2012).
[d] Where Dermal Exposure (mg/kg bw/day) = Exposure (mg/day) / Body Weight (kg). Body weights of 80, 57 and 32 kg were used for adults, youths (11 <16 years), and children (6<11 years) respectively, as stated in the USEPA Residential SOPs (2012).
[e] MOE = margin of exposure; MOE = NOAEL ÷ exposure, based on a dermal NOAEL of 10 mg/kg bw/day and a target MOE of 300 applicable to short- and intermediate-term scenarios.

Table 5 Postapplication Dermal Exposure from Lawns and Turf

Exposure Scenario	Lifestage	TTR [a] ($\mu g/cm^2$)	TC [b] (cm^2/hr)	ET [c] (hr/day)	Dermal Exposure [d] (mg/kg bw/day)	Dermal MOE [e] (rounded)
High Contact Lawn Activities	Adults	6.70E-03	180000	1.5	2.27E-02	440
	Youth 11 <16 yrs		148000	1.3	2.27E-02	440
	Children 1<2 yrs		49000	1.5	4.49E-02	220
Mowing	Adults		5500	1	4.62E-04	22000
	Youth 11<16 yrs		4500		5.31E-04	19000
Golfing	Adults	6.70E-03	5300	4	1.78E-03	5600
	Youth 11 <16 yrs		4400		2.08E-03	4800
	Children 6<11 yrs		2900		2.44E-03	4100

[a] The risk assessment was conducted without chemical-specific TTR since no studies were provided. Default values obtained from USEPA Residential SOPs (2012). Based on 4 applications and a 7 day interval.
[b] Transfer Coefficient (cm^2/hr) default values obtained from the USEPA Residential SOPs (2012).
[c] Exposure Time (hr/day) default values obtained from the USEPA Residential SOPs (2012).
[d] Where Dermal Exposure (mg/kg bw/day) = Exposure ÷ Body Weight. Body weights of 80, 57, 32, and 11 kg were used for adults, youths, children (6 <11 years), and children 1<2 yrs, as stated in USEPA Residential SOPs (2012). Fraction transferred was taken into consideration when calculating residues after multiple applications.
[e] MOE = margin of exposure; MOE = NOAEL ÷ Exposure, based on a dermal NOAEL of 10 mg/kg bw/day and a target MOE of 300 applicable to short- to intermediate-term scenarios. Shaded cells indicate targets not met.

Table 6 Postapplication Hand-to-Mouth Exposure to Children 1<2 years from Indoor Environments – Pressurized Product Formulation

Exposure Scenario		Hand residue loading [a] (mg/cm^2)	Oral Expsoure [b] (mg/kg bw/day)	Incidental Oral MOE [c] (rounded)
Band/Spot/Bedbug (Pin Stream)	Carpet	2.4E-04	6.3E-03	30
	Hard Surfaces	1.6E-04	2.1E-03	90
Crack and crevice (Non-Bedbug)	Carpet	6.5E-05	1.7E-03	110
	Hard Surfaces	4.3E-05	5.8E-04	330

[a] Hand residue loading (HR) is based on the dermal postapplication exposure from indoor applications without the body weight × fraction of a.i. on hands compared to body (0.15).

[b] Where Oral Exposure = [HR × (F_M × SA_H) × (ET × N) × (1 – (1 – SE) $^{FreqH/N}$)] ÷ BW. Exposure times (ET) for carpets and hard surfaces were 4, and 2 hrs, respectively, as stated in the USEPA Residential SOPs (2012). F_M: fraction of hand surface area mouthed/event; SA_H: typical surface area of one hand; N: number of replenishment intervals per hour; SE: saliva extraction factor; FreqH: number of hand-to-mouth events per hour; BW: bodyweight. Defaults were used as stated in the USEPA Residential SOPs (2012).

[c] MOE = margin of exposure; Oral MOE = oral $BMDL_{20}$ ÷ Oral exposure, based on the short-term incidental oral $BMDL_{20}$ of 0.19 mg/kg bw/day and a target MOE of 300. Shaded cells indicate targets not met.

Table 7 Postapplication Hand-to-Mouth Exposure to Children 1<2 years from Indoor Environments – Liquid Formulation

Exposure Scenario		Hand residue loading [a] (mg/cm^2)	Oral Exposure [b] (mg/kg bw/day)	Incidental Oral MOE [c] (rounded)
Band/Spot (Pin Stream)	Carpet	3.5E-04	9.2E-03	21
	Hard Surfaces	2.3E-04	3.1E-03	62
Bedbug treatment [d]	Carpet	1.7E-04	4.6E-03	41
	Hard Surfaces	1.2E-04	1.5E-03	120
Crack and Crevice	Carpet	6.9E-05	1.8E-03	100
	Hard Surfaces	4.6E-05	6.1E-04	310

[a] Hand residue loading (HR) is based on the dermal postapplication exposure from indoor applications without the body weight × fraction of a.i. on hands compared to body (0.15).

[b] Where Oral Exposure = [HR × (F_M × SA_H) × (ET × N) × (1 – (1 – SE) $^{FreqH/N}$)] ÷ BW. Exposure times (ET) for carpets and hard surfaces were 4, and 2 hrs, respectively, as stated in the USEPA Residential SOPs (2012). F_M: fraction of hand surface area mouthed/event; SA_H: typical surface area of one hand; N: number of replenishment intervals per hour; SE: saliva extraction factor; FreqH: number of hand-to-mouth events per hour; BW: bodyweight. Defaults were used as stated in the USEPA Residential SOPs (2012).

[c] MOE = margin of exposure; Oral MOE = oral $BMDL_{20}$ ÷ Oral exposure, based on the short-term incidental oral $BMDL_{20}$ of 0.19 mg/kg bw/day and a target MOE of 300. Shaded cells indicate targets not met.

[d] Bedbug application is defined as pin stream surface application to limited areas as well as crack and crevice application.

Table 8 Postapplication Hand-to-Mouth Exposure to Children 1<2 years from Turf

Exposure Scenario	Hand Residue Loading [a] (mg/cm^2)	Oral Exposure [b] (mg/kg bw/day)	Incidental Oral MOE [c] (rounded)
Turf	9.9E-05	9.2E-04	210

[a] Hand residue loading (HR) is based on the dermal postapplication exposure from indoor applications without the body weight × fraction of a.i. on hands compared to body (0.06).

[b] Where Oral Exposure = $[HR \times (F_M \times SA_H) \times (ET \times N) \times (1 - (1 - SE)^{FreqH/N})] \div BW$. Exposure time (ET) for outdoor scenarios is 1.5 hrs, as stated in the USEPA Residential SOPs (2012). F_M: fraction of hand surface area mouthed/event; SA_H: typical surface area of one hand; N: number of replenishment intervals per hour; SE: saliva extraction factor; FreqH: number of hand-to-mouth events per hour; BW: bodyweight. Defaults were used as stated in the USEPA Residential SOPs (2012).

[c] MOE = margin of exposure; Oral MOE = oral $BMDL_{20} \div$ Oral exposure, based on the short-term incidental oral $BMDL_{20}$ of 0.19 mg/kg bw/day and a target MOE of 300. Shaded cells indicate targets not met.

Appendix VIII Combined Risk (All routes) Assessment of Residential Non-Dietary Exposures

Table 9 Combined Residential Postapplication Exposure – Indoor Environments – Pressurized Product Formulation

Exposure Scenario		Lifestage	Margins of Exposure [a]			
			Dermal	Inhalation	Incidental Oral [b]	Combined
Band/Spot/Bedbug (Pin Stream)	Carpet	Adults	220	880000	n/a	220
		Youth 11 <16 years	310	690000		310
		Children 1 <2 years	230	200000	30	27
	Hard surface	Adults	670	880000	n/a	670
		Youth 11 <16 years	1200	690000		1200
		Children 1 <2 years	350	200000	90	71
Crack and crevice (non-bedbug)	Carpet	Adults	820	880000	n/a	820
		Youth 11 <16 years	1100	690000		1100
		Children 1 <2 years	850	200000	110	97
	Hard surface	Adults	2500	880000	n/a	2400
		Youth 11 <16 years	4200	690000		4200
		Children 1 <2 years	1300	200000	330	260

[a] MOE = margin of exposure; MOE = NOAEL ÷ exposure; Combined MOE = 1 ÷ [(1 ÷ MOE_{derm})+(1 ÷ MOE_{inhal})]; Dermal NOAEL 10 mg/kg bw/day; inhalation NOAEL 0.08 mg/kg bw/day; incidental oral $BMDL_{20}$ of 0.19 mg/kg bw/day; target MOE of 300. Shaded cells indicate targets not met.

[b] Incidental oral exposure combined with dermal and inhalation exposures for Children 1<2 years.

Table 10 Combined Residential Postapplication Exposure – Indoor Environments – Liquid Formulation

Exposure Scenario		Lifestage	Margins of Exposure [a]			
			Dermal	Inhalation	Incidental Oral [b]	Combined
Band/Spot (Pin Stream)	Carpet	Adults	150	20000	n/a	150
		Youth 11 <16 years	210	16000		210
		Children 1 <2 years	160	4700	21	18
	Hard surface	Adults	460	20000	n/a	450
		Youth 11 <16 years	800	16000		760
		Children 1 <2 years	240	4700	62	49
Bedbug treatment [c]	Carpet	Adults	310	20000	n/a	300
		Youth 11 <16 years	420	16000		410
		Children 1 <2 years	320	4700	41	36
	Hard surface	Adults	920	20000	n/a	880
		Youth 11 <16 years	1600	16000		1400
		Children 1 <2 years	480	4700	120	96
Crack and Crevice	Carpet	Adults	770	20000	n/a	740
		Youth 11 <16 years	1100	16000		990
		Children 1 <2 years	800	4700	100	90
	Hard Surface	Adults	2300	20000	n/a	2100
		Youth 11 <16 years	4000	16000		3200
		Children 1 <2 years	1200	4700	310	230

[a] MOE = margin of exposure; MOE = NOAEL ÷ exposure; Combined MOE = 1 ÷ [(1 ÷ MOE_{derm})+(1 ÷ MOE_{inhal})]; Dermal NOAEL 10 mg/kg bw/day; inhalation NOAEL 0.08 mg/kg bw/day; incidental oral $BMDL_{20}$ of 0.19 mg/kg bw/day; target MOE of 300. Shaded cells indicate targets not met.

[b] Incidental oral exposure combined with dermal and inhalation exposures for Children 1<2 years.

[c] Bedbug application is defined as pin stream surface application to limited areas as well as crack and crevice application.

Appendix IX Residential Postapplication Cancer Risk Assessment

Table 11 Residential Postapplication Indoor Combined Cancer Risk Estimates – Pressurized Product Formulation

Use Scenario		Lifestage	Deposited Residue (ug/cm^2)	Transferrable Residue [a] (ug/cm^2)	TC [b]	ET [c] (hr/day)	Average Daily Lifestage Combined Dose [d, e] (mg/kg/day)	Lifetime Average Daily Dose [f] (mg/kg/day)	Lifetime Cancer Risk [g]
Band/ Spot/ Bedbug (Pin stream)	Carpet	Adults	1.10	0.022	4700	8	9.61E-05	1.16E-04	3E-06
		Youth 11 <16 yrs			3900	5	5.55E-06		
		Children 1<2 yrs			1300	4	1.46E-05 [e]		
	Hard surface	Adults	1.10	0.033	4700	2	3.60E-05	4.61E-05	1E-06
		Youth 11 <16 yrs			3900	1	1.67E-06		
		Children 1<2 yrs			1300	2	8.37E-06 [e]		
Crack and crevice	Carpet	Adults	0.30	0.006	4700	8	2.62E-05	3.17E-05	8E-07
		Youth 11 <16 yrs			3900	5	1.51E-06		
		Children 1<2 yrs			1300	4	4.00E-06 [e]		
	Hard surface	Adults	0.30	0.009	4700	2	9.83E-06	1.26E-05	3E-07
		Youth 11 <16 yrs			3900	1	4.55E-07		
		Children 1<2 yrs			1300	2	2.28E-06 [e]		

[a] Where Transferable Residue ($\mu g/cm^2$) = Deposited Residue ($\mu g/cm^2$) × Fraction Transferred (%). Deposited residues were defaults from the USEPA Residential SOPs (2012).

[b] Transfer Coefficient (cm^2/hr) 50th percentile values obtained from the USEPA Residential SOPs (2012).

[c] Exposure Time (hr/day) default values obtained from the USEPA Residential SOPs (2012).

[d] Where Average Daily Lifestage Dose (ADLD) = (Average Daily Dose × Exposure Frequency × Years of Exposure) ÷ (365 d/yr × Life Expectancy); combines exposures from each route (see notes below). Body weights of 80, 57 and 11 kg were used for adults, youths (11 <16 years), and children (1 <2 years) respectively, as stated in the USEPA Residential SOPs (2012). A dermal absorption factor of 14% was applied in the cancer risk assessment. Exposure frequency is 30 days/year.

[e] For Children 1<2 yrs, the ADLD incorporates exposure from dermal, inhalation and incidental oral routes.

[f] Where Lifetime Average Daily Dose (LADD) = $ADLD_{children} + ADLD_{youths} + ADLD_{adults}$.

[g] Where Lifetime Cancer Risk = LADD × q_1*. Based on a q_1* value of 2.66E-02 $(mg/kg\ bw/day)^{-1}$. Shaded cells indicate those Lifetime Cancer Risks that are of concern.

Table 12 Residential Postapplication Indoor Combined Cancer Risk Estimates – Liquid Formulation

Use Scenario		Lifestage	Deposited Residue ($\mu g/cm^2$)	Transferrable Residue [a] ($\mu g/cm^2$)	TC [b]	ET [c] (hr/day)	Average Daily Lifestage Combined Dose [d, e] (mg/kg/day)	Lifetime Average Daily Dose [f] (mg/kg/day)	Lifetime Cancer Risk [g]
Band/ Spot (Pin stream)	Carpet	Adults	1.60	0.032	4700	8	1.40E-04	1.70E-04	5E-06
		Youth 11 <16 yrs			3900	5	8.10E-06		
		Children 1<2 yrs			1300	4	2.14E-05 [e]		
	Hard surface	Adults	1.60	0.048	4700	2	5.27E-05	6.74E-05	2E-06
		Youth 11 <16 yrs			3900	1	2.45E-06		
		Children 1<2 yrs			1300	2	1.23E-05 [e]		
Bedbug Treatment [h]	Carpet	Adults	0.80	0.016	4700	8	7.02E-05	8.50E-05	2E-06
		Youth 11 <16 yrs			3900	5	4.06E-06		
		Children 1<2 yrs			1300	4	1.07E-05 [e]		
	Hard surface	Adults	0.80	0.024	4700	2	2.65E-05	3.39E-05	9E-07
		Youth 11 <16 yrs			3900	1	1.24E-06		
		Children 1<2 yrs			1300	2	6.18E-06 [e]		
Crack and crevice	Carpet	Adults	0.32	0.0064	4700	8	2.82E-05	3.42E-05	9E-07
		Youth 11 <16 yrs			3900	5	1.64E-06		
		Children 1<2 yrs			1300	4	4.35E-06 [e]		
	Hard surface	Adults	0.32	0.0096	4700	2	1.07E-05	1.38E-05	4E-07
		Youth 11 <16 yrs			3900	1	5.12E-07		
		Children 1<2 yrs			1300	2	2.52E-06 [e]		

[a] Where Transferable Residue ($\mu g/cm^2$) = Deposited Residue ($\mu g/cm^2$) × Fraction Transferred (%). Deposited residues were calculated based on maximum label application rates using the USEPA Residential SOPs (2012) algorithms for all scenarios. For band/spot applications, it is assumed that the deposited residue available is 50% of the deposited residue available from broadcast applications (100% of the application rate). It is assumed to be 25% for bedbug treatment, and 10% for crack and crevice.

[b] Transfer Coefficient (cm^2/hr) 50th percentile values obtained from the USEPA Residential SOPs (2012).

[c] Exposure Time (hr/day) default values obtained from the USEPA Residential SOPs (2012).

[d] Where Average Daily Lifestage Dose (ADLD) = (Average Daily Dose × Exposure Frequency × Years of Exposure) ÷ (365 d/yr × Life Expectancy); combines exposures from each route (see notes below). Body weights of 80, 57 and 11 kg were used for adults, youths (11 <16 years), and children (1 <2 years) respectively, as stated in the USEPA Residential SOPs (2012). A dermal absorption factor of 14% was applied in the cancer risk assessment. Exposure frequency is 30 days/year.

[e] For Children 1<2 yrs, the ADLD incorporates exposure from dermal, inhalation and incidental oral routes.

[f] Where Lifetime Average Daily Dose (LADD) = $ADLD_{children} + ADLD_{youths} + ADLD_{adults}$

[g] Where Lifetime Cancer Risk = LADD × q_1^*. Based on a q_1^* value of 2.66E-02 $(mg/kg\ bw/day)^{-1}$. Shaded cells indicate those Lifetime Cancer Risks that are of concern.

[h] Bedbug application is defined as pin stream surface application to limited areas as well as crack and crevice application.

Table 13 Residential Postapplication Outdoor Cancer Risk Estimates – Gardens and Trees

Use Scenario	Lifestage	TWA DFR [a] ($\mu g/cm^2$)	Average Daily Lifestage Dose [b] (mg/kg/day)	Lifetime Average Daily Dose [c] (mg/kg/day)	Lifetime Cancer Risk [d]
Gardens	Adults	0.059	3.08E-05	3.39E-05	9E-07
	Youth 11<16 years		1.39E-06		
	Children 6-11 years		1.72E-06		
Trees	Adults	0.059	5.84E-06	6.42E-06	2E-07
	Youth 11<16 years		2.68E-07		
	Children 6-11 years		3.17E-07		

DFR = dislodgeable foliar residue; TWA = time-weighted average

[a] TWA DFR ($\mu g/cm^2$) calculated based on 3 applications, 7 day intervals, averaged on 30 days exposure

[b] Where Average Daily Lifestage Dose (ADLD) = (Average Daily Dose × Exposure Frequency × Years of Exposure) ÷ (365 d/yr × Life Expectancy). Body weights of 80, 57 and 32 kg were used for adults, youths (11 <16 years), and children (6<11 years) respectively, as stated in the USEPA Residential SOPs (2012). A dermal absorption factor of 14% was applied in the cancer risk assessment. Exposure frequency is 30 days/year.

[c] Where Lifetime Average Daily Dose (LADD) = $ADLD_{children} + ADLD_{youths} + ADLD_{adults}$

[d] Where Lifetime Cancer Risk = LADD × q_1*. Based on a q_1* value of 2.66E-02 $(mg/kg\ bw/day)^{-1}$. Shaded cells indicate those Lifetime Cancer Risks that are of concern.

Table 14 Residential Postapplication Outdoor Lifetime Cancer Risk – Turf

Exposure Scenario	Lifestage	TWA TTR [a] ($\mu g/cm^2$)	Average Daily Lifestage Combined Dose [b] (mg/kg/day)	Lifetime Average Daily Dose [c] (mg/kg/day)	Lifetime Cancer Risk [d]
High Contact Lawn Activities	Adults	0.004	1.26E-04	1.59E-04	4E-06
	Youth 11 <16 yrs		1.00E-05		
	Children 1<2 yrs		2.27E-05		
Mowing	Adults	0.004	2.57E-06	2.80E-06	7E-08
	Youth 11<16 yrs		2.34E-07		
Golfing	Adults	0.004	9.90E-06	1.19E-05	3E-07
	Youth 11 <16 yrs		9.15E-07		
	Children 6<11 yrs		1.07E-06		

TTR = turf tranfserable residue; TWA = time-weighted average

[a] TWA TTR ($\mu g/cm^2$) calculated based on 4 applications, 7 day intervals, averaged on 30 days exposure.

[b] Where Average Daily Lifestage Dose (ADLD) = (Average Daily Dose × Exposure Frequency × Years of Exposure) ÷ (365 d/yr × Life Expectancy); for adults/youth/children (6<11 years), based on dermal route alone; for children (1<2 years), combines exposures from dermal and incidental oral routes. Body weights of 80, 57, 32 and 11 kg were used for adults, youths (11 <16 years), children (6<11 years), and children (1<2 years) respectively, as stated in the USEPA Residential SOPs (2012). A dermal absorption factor of 14% was applied in the cancer risk assessment. Exposure frequency is 30 days/year.

[c] Where Lifetime Average Daily Dose (LADD) = $ADLD_{children} + ADLD_{youths} + ADLD_{adults}$.

[d] Where Lifetime Cancer Risk = LADD × q_1*. Based on a q_1* value of 2.66E-02 $(mg/kg\ bw/day)^{-1}$. Shaded cells indicate those Lifetime Cancer Risks that are of concern.

Appendix X Agricultural and Structural Mixer/Loader/Applicator and Postapplication Risk Assessment

Table 15 Summary of Mixer/Loader/Applicator exposure, non-cancer, and cancer risk assessment

Application Equipment	Scenario	Margins of Exposure[a] (Target = 300)			Cancer Risk[c]
		Dermal	Inhalation	Combined[b]	
BASELINE PPE: single layer, gloves, open cab (if applicable)					
Groundboom – Farmer	MLA	3127	822	651	3E-07
Groundboom – Custom (except legumes)	MLA	1732	455	361	7E-07
Groundboom – Custom (legumes)	MLA	929	244	193	1E-06
Aerial – Forestry	ML	2930	749	597	3E-07
	A	15513	17126	8140	6E-08
Aerial – Agriculture	ML	1564	400	319	1E-06
	A	8282	9143	4345	2E-07
Airblast (except outdoor ornamentals)	MLA	419	1198	310	1E-06
Airblast (outdoor ornamentals)	MLA	388	1110	287	1E-06
Mechanically-pressurized handgun; or ROW sprayer, turf sprayer (except outdoor ornamentals)	MLA	1861	551	425	1E-06
Mechanically-pressurized handgun (outdoor ornamentals)	MLA	140	41	32	1E-06
Manually-pressurized hand wand; or Backpack	MLA	18845	3147	2696	1E-07
Dipper gun	A	12358	2063	1768	2E-07
Aerosol /injection system (Structural sites)	A	1310	588	406	5E-07
Liquid / injection system (Structural sites)	MLA	18845	3147	2696	4E-08

M/L = mix/load; A = application; NOAEL = no observed adverse effect level; MOE = margin of exposure; ROW = rights-of-way sprayer; ATPD = area treated per day; shaded cells indicate MOEs of concern.

[a] Based on a dermal NOAEL of 10 mg/kg bw/day and inhalation NOAEL of 0.08 mg/kg bw/day; Dermal exposure = (dermal unit exposure × ATPD × max app rate) / 80 kg body weight; Inhalation exposure = (inhalation unit exposure × ATPD × max app rate) / 80 kg body weight.

[b] Combined MOE = $1 \div [(1 \div MOE_{derm}) + (1 \div MOE_{inhal})]$; shaded cells indicate target MOE not met.

[c] Cancer risk = lifetime average daily dose × q^*

Table 16 Summary of Occupational Postapplication Non-Cancer Dermal Risk Assessment

Crop / Surrogate / Activities	Rate (kg a.i./ha)	Peak DFR [a] (µg/cm^2)	TC (cm^2/ hr)	Applications Per year	Interval between Applications (days)	MOE[b] (day 0)	REI[c] (proposed)	MOE at REI[d]
Broccoli, Brussels sprouts, Cauliflower								
Scouting	0.023	0.098	4000	3	7	255	2 days	315
Hand weeding			4400			232	3 days	319
Handset irrigation			5150			198	4 days	302
Cabbage, Chinese napa cabbage								
Hand weeding	0.023	0.098	4400	3	7	232	3 days	319
Corn (seed)								
Hand detasseling	0.025	0.13	8800	3	4	87	12 days	308
Corn (sweet and pop)								
Hand harvesting	0.025	0.13	8800	3	4	87	12 days	308
Onion (dry/bulb; green/Welsh), garlic								
Hand weeding	0.023	0.098	4400	3	7	232	3 days	319
Remaining orchard / field crops								
Handset irrigation	0.028	0.148	1750	3	4	385	12 hours	n/a
Forestry / woodlots / shelterbelts								
Hand harvesting	0.010	0.043	6700	3	7	345	12 hours	n/a
Turf (sod farms)								
Harvesting (slab), transplanting/ planting	0.037	0.0045	6700	4	7	3283	12 hours	n/a
Greenhouse crops [e]								
All activities	0.01	0.075	230	3	7	5797	12 hours	n/a
Outdoor ornamentals, excluding cut flowers								
All activities	0.027	0.105	1750	3	7	543	12 hours	n/a
Outdoor ornamentals, cut flowers								
All activities	0.027	0.105	4000	3	7	238	3 days [f]	325

DFR = dislodgeable foliar residue; TC = transfer coefficient; MOE = margin of exposure; REI = re-entry interval; n/a = not applicable.

[a] Peak default DFR rate of 25% of application rate used (with 10% dissipation per day).

[b] Based on a dermal NOAEL of 10 mg/kg bw/day and target MOE of 300; shaded cells indicate estimates of concern.

[c] If target MOE is met, REI is set at 12 hours.

[d] MOE at proposed REI.

[e] Peak default DFR rate of 25% of application rate used (with 0% dissipation for greenhouse lettuce and 2.3% dissipation for greenhouse tobacco seedlings).

[f] As the original REI of 6 days was put on the label as a result of a previous PMRA review, PMRA can now propose changing it to 3 days based on the current re-evaluation. However, it will be clarified that the REI is for all activities with cut flowers, not for cutting flowers.

Table 17 Occupational Postapplication Cancer Risk Estimates

Use Scenario	Activity	TWA DFR [a] ($\mu g/cm^2$)	Lifetime Average Daily Dose [b] (mg/kg/day)	Dermal Cancer Risk [c]
Broccoli; cavolo broccolo; Brussels sprouts, cauliflower; Chinese broccoli (gai lon)	Harvesting (hand)	0.050	1.5E-04	4E-06
Cabbage; Chinese cabbage mustard (gai choy); Chinese napa cabbage; kohlrabi; onion (dry bulb/green/Leeks); garlic; shallots	Weeding (hand)		1.3E-04	3E-06
Corn (sweet/pop/seed)	Detasseling or Harvesting (hand)	0.057	2.9E-04	8E-06
Outdoor ornamentals, cut flowers	All activities	0.054	1.3E-04	3E-06

DFR = dislodgeable foliar residue; TWA = time-weighted average.

[a] TWA DFR ($\mu g/cm^2$) calculated based on 30 days exposure.

[b] Where Lifetime Average Daily Dose (LADD) = (Dermal exposure dose × Exposure Frequency × Years of Exposure) ÷ (365 d/yr × Life Expectancy). Body weight of 80 kg was used for adults. A dermal absorption factor of 14% was applied in the cancer risk assessment.

[c] Where Cancer Risk = LADD × q_1*. Based on a q_1* value of 2.66E-02 $(mg/kg\ bw/day)^{-1}$.

Appendix XI Aggregate (All Routes and Pathways) Risk Assessment

Table 18 Lambda-cyhalothrin Non-Cancer Aggregate Risk Assessment for Outdoor Uses

Use Scenario	Lifestage	DFR or TTR ($\mu g/cm^2$)	Margins of Exposure [a]		
			Dermal MOE	Dietary MOE	Aggregate
Gardens	Adults	0.115[b]	380	50000	370
	Youth 11<16 years		330	100000	320
	Children 6<11 years		550	50000	540
Trees	Adults	0.115[b]	4100	50000	3800
	Youth 11<16 years		3500	100000	3400
	Children 6<11 years		6000	50000	5300
Golfing	Adults	0.0067[c]	5600	50000	5000
	Youth 11<16 years		4800	100000	4600
	Children 6<11 years		4100	50000	3800

[a] MOE = margin of exposure; MOE = NOAEL ÷ exposure; Dermal NOAEL 10 mg/kg bw/day; inhalation NOAEL 0.08 mg/kg bw/day; dietary NOAEL 0.1 mg/kg bw/day; target MOE of 300. Aggregate MOE = $1 \div [(1 \div MOE_{dermal}) + (1 \div MOE_{dietary})]$.

[b] Dislogdeable foliar residue (DFR) ($\mu g/cm^2$) calculated based on 3 applications, 7 day intervals

[c] Turf transferable residue (TTR) ($\mu g/cm^2$) calculated based on 4 applications, 7 day intervals

Table 19 Lambda-cyhalothrin Cancer Aggregate Risk Assessment for Outdoor Uses

Use Scenario	Lifestage	TWA DFR or TTR ($\mu g/cm^2$)	Average Daily Lifestage Aggregate Dose [c] (mg/kg bw/day)	Lifetime Average Daily Dose [d] (mg/kg bw/day)	Lifetime Aggregate Cancer Risk [e]
Gardens	Adults	0.059 [a]	3E-05	4E-05	1E-06
	Youth 11<16 years		2E-06		
	Children 6<11 years		4E-06		
Trees	Adults	0.059 [a]	8E-06	1E-05	3E-07
	Youth 11<16 years		1E-06		
	Children 6<11 years		2E-06		
Golfing	Adults	0.0040 [b]	1E-05	2E-05	4E-07
	Youth 11<16 years		2E-06		
	Children 6<11 years		3E-06		

[a] Time-weighted average DFR ($\mu g/cm^2$) calculated based on 3 applications, 7 day intervals, 30 days exposure

[b] Time-weighted average TTR ($\mu g/cm^2$) calculated based on 4 applications, 7 day intervals, 30 days expsosure

[c] Where aggregate ADLD = (Average Daily Dose × Exposure Frequency × Years of Exposure) ÷ (365 d/yr × Life Expectancy); combines exposures from the dermal and dietary routes. Body weights of 80, 57 and 32 kg were used for adults, youths (11 <16 years), and children (6<11 years) respectively, as stated in the USEPA Residential SOPs (2012). A dermal absorption factor of 14% was applied in the cancer risk assessment. Exposure frequency is 30 days/year.

[d] Where Lifetime Average Daily Dose = $ADLD_{children} + ADLD_{youths} + ADLD_{adults}$.

[e] Where Lifetime Aggregate Cancer Risk (LCR) = LADD × q_1*. Based on a q_1* value of 2.66E-02 $(mg/kg\ bw/d)^{-1}$.

Table 20 Lambda-cyhalothrin Non-Cancer Aggregate Risk Assessment using Biomonitoring Data

Pyrethroid	Specific Metabolite Daily Excretion [a] (µg/kg bw/day)	Parent Equivalent [b] (µg/kg bw/day)	MOE [c] (Target MOE = 300)
Canadian Health Measures Survey (CHMS) - Canada			
General Population	0.00775	0.65	154
Children (3-5 yrs)	0.215	1.81	55 [d]
Children (6-10 yrs)	0.0507	0.43	235
Youth (11-15 yrs)	0.0601	0.50	198
Adults (16-79 yrs)	0.0804	0.68	148
MIREC [e] - Canada			
Children (<3 yrs)	0.119	1.00	100

[a] CHMS data was used for adults, youth and children older than 3. MIREC data was used for children under 3 years old. The 95th percentile values were used in the risk assessment, except for where the coefficient of variation (CV) was greater than 33% in the CHMS data. For these values, the upper 95% confidence bound of the 95th percentile was used in the risk assessment, as is recommended by Statistics Canada for the CHMS data. 3-PBA was used in the assessment for lambda-cyhalothrin.

[b] Parent equivalent = [specific metabolite daily excretion (µg/kg bw/day) × (MW_{parent} ÷ $MW_{metabolite}$)] ÷ F_{ue} (%), where MW is molecular weight (lambda-cyhalothrin 449.85 g/mol; 3-PBA 214.22 g/mol); F_{ue} is the urinary excretion fraction, based on human pharmacokinetic studies (25% for lambda-cyhalothrin).

[c] MOE = NOAEL ÷ (parent equivalent × 1000 mg/µg). NOAEL = 0.1 mg/kg bw/day. Shaded cells indicate where MOEs are less than the target MOE.

[d] The CV was greater than 33% for this value, so the upper 95% confidence bound on the 95th percentile was used.

[e] The 95th percentile was used in the non-cancer risk assessment.

Table 21 Summary of Cancer Aggregate Exposure and Risk Assessment using Biomonitoring Data

Lifestage	Specific Metabolite Daily Excretion [a] (µg/kg bw/day)	Average Daily Lifestage Dose [b] (µg/kg bw/day)	Lifetime Average Daily Dose [c] (µg/kg bw/day)	Lifetime Cancer Risk [d]
General Population (6-79 years)	0.0297	0.23	0.261	7×10^{-6}
Children (3-5 years)	0.0581	0.031		

[a] CHMS data was used for adults and children (3-5 years). Arithmetic mean values were used except for where the coefficient of variation was greater than 33%. For these values, the upper 95% confidence bound of the arithmetic mean was used in the risk assessment, as is recommended by Statistics Canada for the CHMS data.

[b] Average daily lifestage dose (ADLD) = [specific metabolite daily excretion (µg/kg bw/day) × ($MW_{parent} \div MW_{metabolite}$) × exposure duration] ÷ [F_{ue} (%) × life expectancy (78 years)], where MW is molecular weight (lambda-cyhalothrin 449.85 g/mol; 3-PBA 214.22 g/mol); F_{ue} is the urinary excretion fraction, based on human pharmacokinetic studies (25% for lambda-cyhalothrin); exposure duration for adults is 74 years and children 5 years.

[c] Lifetime average daily dose = $ADLD_{gen\ pop} + ADLD_{children\ (<6\ years)}$.

[d] Lifetime Cancer Risk = LADD × (1÷1000 µg/mg) × q_1*. Based on a q_1* value of 2.66E-02 (mg/kg bw/day)$^{-1}$. Shaded cells indicate where the cancer risk is greater than 1×10^{-6}.

Appendix XII Environmental Exposure and Risk Assessment for Lambda-cyhalothrin

Table 1 Major groundwater and surface water model inputs for Level 1 assessment of lambda-cyhalothrin

Type of Input	Parameter	Value
Application Information	Crop(s) to be treated	Many food and non-food crops
	Maximum allowable application rate per year (g a.i./ha)	148 for turf 85.278 for soybeans 5.04 for tobacco
	Maximum rate each application (g a.i./ha)	37 for turf 28.426 for soybeans 5.04 for tobacco
	Maximum number of applications per year	4 for turf 3 for soybeans 1 tobacco
	Minimum interval between applications (days)	7 for turf 4 for soybeans
	Method of application	Foliar, ground and aerial
Environmental Fate Characteristics	Hydrolysis half-life at pH 7 at 25 °C(days)	91.6
	Photolysis half-life in water at 25 °C(days)	12.2
	Adsorption K_{OC} (mL/g)	95355 (20^{th} percentile of 14 K_{OC} values for "lambda-cyhalothrin")
	Aerobic soil biotransformation half-life at 25°C(days)	4823 (90^{th} percentile confidence bound on mean of 8 half-lives adjusted to 25°C)
	Aerobic aquatic biotransformation half-life at 25°C(days)	35.4 (80^{th} percentile of 5 half-lives)
	Anaerobic aquatic biotransformation half-life at 25°C(days)	89.4 (80^{th} percentile of 3 half-lives)

Table 2 Level 1 Estimated Environmental Concentrations of lambda-cyhalothrin in potential sources of drinking water

Crop (use pattern)	Groundwater (µg a.i./L)		Surface Water (µg a.i./L)	
			Reservoir	
	Daily[1]	Yearly[2]	Daily[3]	Yearly[4]
Turf (4 × 37 g a.i./ha at 7 day intervals)	0	0	1.2	0.13

[1] 90th percentile of daily average concentrations
[2] 90th percentile of yearly average concentrations
[3] 90th percentile of yearly peak concentrations
[4] 90th percentile of yearly average concentrations

Table 3 Fate and Behaviour in the Terrestrial Environment

Property	Value		Major Transformation products	Comments	PMRA#
Abiotic transformation (DT_{50})					
Hydrolysis	Study values:	PMRA calculated values:	Transformation products Ia, IV, V	Important route of dissipation under alkaline conditions	1249069 1348014
	pH 5 stable pH 7 stable pH 9=7 d	pH 7, 25°C: DT50 = 87.4 d and 92.6 d			
	pH 7, 25°C: DT50=87.4 d pH 7, 35°C: DT50=42.9 d pH 9, 25°C: DT50=1.3 d pH 9, 35°C: DT90=0.2 d pH 4: stable pH 7 20°C: DT50=167.18 d pH 9 20°C: DT50=17.76 d				2552956 2635520

Phototrans-formation on soil	Stable DT50=53.7 d				Not an important route of dissipation in the environment	1215780 1348014 1249064 2513989
Biotransformation						
Biotrans-formation in aerobic soil	**Soil**	**Study value DT50/90:**	**PMRA DT50/90/t_R:**	Transformation product Ia, transformation product XV, transformation product V	Slightly persistent to persistent	2635520
	18 Acres sandy loam	19.7/2330 (lowrie 2011a) 17.5/323 (Mackenzie 2011a)	17.5/323/141			
	Nebraska loam	36.9/123 (Mackenzie 2011a) 19.8/158 (Lowrie 2011a)	20.1/154/58.3			
	Gartenacker loam	7.4/28.8 (Mackenzie 2011a) 7.8/26 (Mackenzie 2011a)	7.2/31/9.3			
	Marsillargues silty clay	24.8/82 (Mackenzie 2011a) 16.2/141.7 (Mackenzie 2011a)	16/110/42.4			

	Speyer 5M sandy loam	49.4/164 (RMS recalc of Adams 2012c and d) 27.5/274.7 (RMS recalc of Adams 2012c and d)	28.6/285/120 (combined from two studies)			
	Am Fischteich silt loam	108/359 (RMS recalc of Adams 2012c) 59.8/not calc (RMS recalc of Adams 2012c)	68.1/1683/696			
	Lohmingen loam	248/824 (Adam 2012d)	9578/60509/2.19x10^{-4}			
	Speyer 2.2 loamy sand	163/541(RMS recalc of Adams 2012c) 303/934000 (RMS recalc of Adams 2012c)	417/2718/991			
Biotrans-formation in anaerobic soil	74 d (20 °C)			Transformation products Ia and V	Moderately persistent	1348014
	101 d					2542356

	99d (sandy loam) (20 °C) 134 d (sandy clay loam) (20 °C)			2635520
Mobility				
Adsorption / desorption in soil	**Soil/location**	**Study Koc**	**PMRA Koc**	Strong affinity to soil; immobile 1348014 2552956 2635520
	18 Acres sandy clay loam	**70100** (Vickers and Bewick 1986)	45241	
	Frensham sandy loam	103800 (Vickers and Bewick 1986)	59689	
	Vicsburg	430000 (Vickers and Bewick 1986)	388419	
	Goldsboro	132200 (Vickers and Bewick 1986)	101348	
	Hyde Farm sandy clay loam	346000 (Muller et al 1996)	283355	
	East Anglia loamy sand	200000 (Muller et al 1996)	206650	
	Wisborough silty clay loam	298000 (Muller et al 1996)	282685	
	ERTC loamy sand	724000 (Muller et al 1996)	617467	
	NRTC silty clay loam	209000 (Muller et al 1996)	200571	
	Virginia waters sandy loam	270000 (Muller et al 1996)	139812	
	"Mesocosm" sandy loam	305000 (Muller et al 1996)	363036	
	Millstream loamy sand	352000 (Muller et al 1996)	338310	
	Iron Hatch Sand	518000 (Muller et al 1996)	504600	
	Old Basing sandy loam	110000 (Muller et al 1996)	86366	
Soil leaching	No leaching observed below 5 cm depth			Low potential for 1348014

			leaching	
	Less than 0.65 µg/L found in all but one replicate soil column, in which 0.86 µg/L was found in the leachate.			2552956
Field studies (DT_{50})				
Field dissipation	33-39 d (United States) 53-55 d (Canada)	Slightly persistent based on Canadian data	1181654 1216257 1348014	
	6-40 d (United States) 2-37 d (Germany; supplemental data)		2542356	
	7.9-45.4 d (United S) 10-47.5 d (Germany; supplemental data)		2552956 2635521 2635520	

Table 4 Fate and behaviour in the aquatic environment

Study type	Test material	Value		Transformation products	Comments	PMRA#
Abiotic transformation (DT_{50})						
Hydrolysis	Technical	**Study values:**	**PMRA calculated values**			
		pH 5 stable pH 7 stable pH 9=7 d	pH 7, 25°C: 87.4 d and 92.6 d	Transformation products Ia, IV, V	Important route of dissipation under alkaline conditions	1249069 1348014
		pH 7, 25°C: DT50=87.4 d pH 7, 35°C: DT50=42.9 d pH 9, 25°C: DT50=1.3 d pH 9, 35°C: DT90=0.2 d pH 4: stable pH 7 20°C: DT50=167.18 d pH 9 20°C: DT50=17.76 d				2552956 2635520

Phototransf-ormation in water	Technical	~30 d 20-23 d 8.5 to 11.4 d 5 d (summer) 75 d (winter) 24.5 d	Transformation products Ia and V	Can contribute to the dissipation of lambda-cyhalothrin within the photic zone of aquatic environments	1218898 1248988 1348014 2635520 2552956 2542356 1163876 2513989
Biotransformation					
Biotransfor mation in aerobic water systems	Technical	**Study DT50s:** / **PMRA DT50/90/t_R:**			
		12.6-60 d (whole system) / 12.6-60 d (DT50 whole system)	Transformation products Ia and XV	Non to moderately persistent	2546931
		21.9 d			2513989
		7-15 d (whole system)			2542356
		Old basing sandy loam (whole system): 21 d (water): 0.19 d / 17/137/41.4			2552956 2635520
		Virginia water sand (whole system): 10.9 d (water): 0.28 d / 12.6/42/12.6			

Biotransformation in anaerobic water systems	Technical	**Study DT50s:** System 1 (sand, OC 0.6%): 84 d System 2 (clay, OC 7.4%): 93 d System 3 (sandy clay loam, OC 2.7%: 62 d	**PMRA DT50/90/t_R:** System 1 (sand, OC 0.6%): 84 d DT50 System 2 (clay, OC 7.4%): 93 d DT50 System 3 (sandy clay loam, OC 2.7%: 62 d DT50	Transformation products were not measured	Moderately persistent	2546931
Field studies						
Field dissipation	lambda-cyhalothrin dissipates rapidly from the water phase and has a high potential for soprtion to aquatic plant tissue and sediment.					1348014 2552956
Bioaccumulation						
BCF values of 1500 to 2000 were determined for *Chironomus riparius* in a water only systems, with 48 h aqueous BCF ranging from 1300 or 3400 in sediment/water systems. BCF values ranging from 3952 to 6691 were reported for fathead minnow, with an overall mean BCF of 4982 based on measured concentrations of lambda-cyhalothrin. Carp study yielded a BCF of 2000 after 2 weeks of a 28 day exposure period, with 78% of residues being eliminated during the subsequent 28 day depuration period.						2552956 2235719 1348014

Table 5 Effects on terrestrial organisms

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	PMRA#
Invertebrates					
Earthworm	14 d Acute	Technical	LC_{50}>1000 mg/kg soil[1]		2542356 2635522
	56 d		LC_{50} >100 mg/kg soil NOEC=12.5 mg kg/soil (growth) NOEC=6.25 mg kg/soil (reproduction))		
	14 d	Transformation product XV	LC_{50}>1000 mg/kg soil		
	56 d		LC_{50}>100 mg/kg soil (mortality) 100 mg/kg soil (growth and reproduction)		
	56 d	Transformation product Ia	LC_{50}>100 mg kg/soil (mortality) NOEC=25 mg/kg soil (growth) NOEC=6.25 mg/kg soil (reproduction)		
		Transformation product V	LC_{50}>100 mg kg/soil (mortality) NOEC=25 mg/kg soil (growth) NOEC=6.25 mg/kg soil (reproduction)		
Bee	24 h-Oral	Technical Formulated	LD_{50}=0.965 µg a.i./bee LD_{50}=0.57 µg a.i./bee	Highly toxic	1249013 1249014 2513991
	24 h-Contact 48 h-Contact	Technical Formulated Formulated	LD_{50}=0.051 µg a.i./bee LD_{50}=0.095 µg a.i./bee LD_{50}=0.038 µg a.i./bee		
	Foliage residue toxicity	Formulated	LT_{50}=8 hr @ 15 g a.i./ha LT_{50}=24 hr @ 35 g a.i./ha NOEL=24-48 hr @ 15 g a.i./ha	N/A	1218905 2235676

			NOELThe NOEL was not reached at 96 hr @ 35 g a.i./ha		
	Semi-field	Karate WG (applied to winter wheat at 15 g a.i./ha during bee flight)	- No negative effects on the development of bee brood and the bees in the colony. Repellency effect for 24 hr. - Increased mortality post- application in first test, and slight increase in mortality on day of application only for second test. -No negative influence on the development of the bee brood and the bees in the colony.	N/A	2235677
		Karate WG (applied to winter wheat at 7.5 and 15 g a.i./ha during bee flight) applied to half the crop	- No significant increase in mortality or foraging. Trend of higher mortality in treatment tents compared to control. -Repellency effect up to 3 days. -No negative influence on the development of the bee brood.		2235681
	Field Study	Karate EC (applied to oil seed rape at 10 g a.i./ha) during bee flight	-no effects on mortality. -no effects on brood development. - 1.5 hour foraging inhibition, thought to be as a result of repellency	N/A	1249017
		Karate WG EC (applied to winter wheat at 45 g a.i./ha **after** bee flight)	No repellant effects noted. When applied in the evening, following the daily bee-flight, no noticeable effect on mortality, bee brood and forager bees.		2235678
		Karate WG (applied to winter wheat at 45 g a.i./ha during bee flight)	-flight intensity was reduced. -no negative influence on brood development of the bee brood -mortality slightly higher after exposure, but similar		2235680

			between control and treatment on a per day basis. - paralysis observed on day of treatment in some bees		
		Karate WG (applied to winter wheat at 45 g/ha) during bee flight	-mortality higher on first day of exposure -paralysis observed -flight intensity was reduced -author indicated that "poisoning" effects were observed but reversible, as bees recovered after 2 hours. -no negative influence on brood		2235689
		Karate WG (applied at 20 and 25 g a.i./ha to oil seed rape) during bee flight	-flight intensity was reduced on day of application only at both rates -at both rates mortality was slightly higher 2 days after exposure, and reached maximum on day of exposure. -no negative influence on brood		2235682
		Karate WG (applied at 7.5 g a.i./ha to oil seed rape) during bee flight.	-no mortality on bees foraging on flowering oilseed rape. -slight decrease in foraging for 2 days -no negative influence on brood		2235683
		Karate CS (applied at 15 g a.i./ha to oil seed rape) during bee flight.	-repellent effect directly after application. -Increased mortality on day of application. -no negative influence on brood (however, all hives were preparing for overwintering)		2235684
		Karate CS (applied at 7.5 and 15 g a.i./ha to oil seed rape) during bee flight	- Negligible increase in mortality at 7.5 g and obvious increase at 15 g a.i./ha. At both rates the mortality reached maximum on the treatment day. -apparent repellent effect - no negative influence on brood		2235685

		Karate CS (applied at 7.5 and 15 g a.i./ha to oil seed rape) during bee flight	- slightly higher number of dead bees in the low dose and a much higher number of dead bees in the high dose. -repellant effect at both rates -no negative influence on brood		2235686
		Karate WG (applied at 20 and 25 g a.i./ha to oil seed rape) during bee flight	- No significant increased in mortality at 20 g a.i./ha. Noticable mortality occurred at 25 g a.i./ha. -Flight intensity decreased at both application rates. -no negative influence on brood		2235688

Predatory arthropod	Tier I: 7d-Contact, glass plates *(Typhlo dromus pyri)* Extended Laboratory Studies: 14 day extended lab study, bean leaf discs *(Typhlodromus pyri)*	Karate CS CS formulation	LR50=0.0037g a.i./ha (glass plates) LR50= 0.0094 g a.i./ha (as determined by RMS) ; NOAER for reproduction= 0.009 mg a.i./ha (highest rate tested for sublethal effects)	N/A	2635522 2235690 2635522 2235691 1463343
	14 day contact, extended lab study, bean leaf discs *(Typhlodromus pyri)*	Lambda 50 EC	LR50=0.0017 g a.i./ha; NOAER for reproduction= 0.0009 g a.i./ha		2635522
	9d-Contact, extended lab study, bean leaves *(Orius insidiosus)*	CS formulation	LR50=0.0179 g a.i./ha; NOAEL for reproduction=0.0201 g a.i./ha		2635522 2235693 1464949
	27d-Contact, extended lab	CS formulation	LR50=4.3 g a.i./ha; NOAL for reproduction= 2 g		2635522

	study, bean leaves (*Chrysoperla carnea*)		a.i./ha (highest rate tested)		2235694
Parasitic arthropod	Tier I: 48h-Contact, glass plates *(Aphidius rhopalosiphi)* Extended laboratory tests: 28d-Contact, extended lab study, soil substrate *(Aleochara bilineata)* Extended lab study, barley plants (*Aphidius rhopalosiphi*)	CS Formulation	LC_{50}=1.06 g a.i./ha NOEC=0.5 g a.i./ha (sublethal effects) ER50=5.5 g a.i./ha (based on reproduction data) LR50=0.35 g a.i./ha NOAER for reproduction=0.5 g a.i./ha (highest rate tested)	N/A	2635522 2235695 2635522 2235692 2635522 2235696
Beneficial Arthropods Comunity	Field	Karate CS and WG	5 g a.i./ha: No chronic effect on arthropod and aphid population in the summer following autum application. 7.1 g a.i./ha: Applied in June to winter wheat. Effects up to 27 weeks. No long term effects other than with spider species	N/A	2635522 2235697 2235699

			2.5, 5,10 g a.i./ha: Short term effects observed. No significant long term effects on arthropod population. 3x10 g a.i./ha (14d interval): Some immediate reduction in the population on different crops. Recovery later in the season or before the next season (Germany, Italy, Denmark) according to authors; RMS did not agree – recovery could not be confirmed. PMRA agrees with RMS.		2235700 2235701 2235702 2235703 2235704 2235705 2235706
Birds					
Bobwhite quail	Acute	Technical	No data available		
	5d-Dietary		LC_{50}>5300 mg/kg diet, equivalent to an LD50 of >530 mg a.i./kg bw/d; NOEL = 530 mg a.i./kg bw/d (highest dose tested)	Practically non-toxic	1249000 2513991 2542356 2552956 2635522
	Reproduction		No directly applicable data were available		
Mallard duck	Acute	Technical	LD_{50}>3950 mg/kg bw	Practically non-toxic	1248998 2513991 2542356 2552956 2635522
	20-wks-Reproduction		NOEC = 30 mg/kg diet (highest concentration tested); equivalent to daily dietary doses of 3.3 and 3.6 mg a.i./kg bw/day for males and females, respectively	No effects on repro-duction	1235033 2513991 2542356 2552956 2635522

Mammals					
Rat	Acute oral	92.6-96% (corn oil)	LD_{50}=56 mg/kg bw (♀) LD_{50}=79 mg/kg bw (♂)	Highly to moderately toxic	2513991
		97.17% 87.72% (corn oil)	LD_{50}=5-50 mg/kg bw LD_{50}=91 mg/kg bw		2542356 1248871 2513991
	90-d Dietary	96.5%	NOAEL = 50 mg a.i./kg diet (equivalent to 5 mg/kg bw/d (♂/♀)) (decreased weight gain and food consumption)	N/A	1248880 2513991
	Reproduction		NOAEL = 1.5-1.9 mg cyhalothrin/kg bw/d (corresponds to 0.75 to 0.95 lambda-cyhalothrin) (reduced adult weight gain and decreased litter weight)(reported as ~2 mg/kg bw/d in PMRA# 2513991 (EFFECT?)	N/A	2513991 2542356 2635521 2665311
	Dermal		LD_{50}=632 (♀) mg/kg bw LD_{50}=696 (♂) mg/kg bw	N/A	1248872 2542356
Rat	Acute oral and dermal	Transformation product Ia	LD_{50} > 4990 mg/kg bw (oral) LD_{50} > 2000 mg/kg bw (dermal)	N/A	2552956
Rat	Acute oral	Transformation product V	LD_{50} = 3000 mg/kg soil	N/A	2552956
Mouse	Acute oral	96.5% (corn oil)	LD_{50} = 19.9 mg/kg bw (♂/♀)	Highly toxic	1248869 2513991 2552956
		87.72% (corn oil)	LD_{50} = 44 mg/kg bw		2513991
	Reproduction		No data available		
Vascular plant	Vegetative vigour	Lambda 50 EC	NOEC = 30 g a.i./ha	N/A	2552956

		Lambda 100 CS	NOEC = 30 g a.i./ha		2635521
		Kaiso sorbie 5% EG	NOEC = 7.5 g a.i./ha		2675970

[a] Atkins et al.(1981) for bees and USEPA classification for others, where applicable

[1] EFSA assessment corrected this value by a factor of 2 based on Pow>2. The original RMS review (Sweden) used current value without correction, where applicable (i.e., 14 d LC_{50} >1000 mg lambda-cyhalothrin/kg soil and NOEC = 100 mg lambda-cyhalothrin/kg soil) .

Table 6 Refined risk assessments of lambda-cyhalothrin for terrestrial non-target arthropods

Organism	Exposure	Endpoint value	EEC	RQ	Level of concern
Predatory mite (*Typhlodromus pyri*)	Extended laboratory	LR_{50} = 0.0017 g a.i./ha	In-field: (foliar interception = in field EECx0.9) 4.54 g a.i./ha (sunflower) 74.1 g a.i./ha (turf)	In-field: **2671** **43588**	 **Exceeded** **Exceeded**
			Off field: (in field EEC × 0.1) 0.03 g a.i./ha (sunflower) 0.49 g a.i./ha (turf)	Off-field: **18** **288**	 **Exceeded** **Exceeded**
A. rhopalosiphi (aphid parasitoid) foliar dwelling parasite	Extended laboratory	LR_{50} = 0.35 g a.i./ha	In-field: (foliar interception = in field EECx0.9) 4.54 g a.i./ha 74.1 g a.i./ha	In-field: **13** **212**	 **Exceeded** **Exceeded**
			Off-field: (off field EEC × 0.1) 0.03 g a.i./ha 0.49 g a.i./ha	Off-field: 0.09 **1.4**	 Not Exceeded **Exceeded**

Values in bold exceed Level of concern (≥ 1)

Table 7 Expanded risk assessment of lambda-cyhalothrin for birds based on the highest seasonal ground application -turf (4 × 37.0 g a.i./ha with a 7 day interval).

			Maximum nomogram residues				Mean nomogram residues			
			On-field		Off Field		On-field		Off Field	
	Toxicity (mg a.i./kg bw/d)	Food Group/Guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Small Bird (0.02 kg)										
Reproduction	3.45	Insectivore	6.71	**1.94**	0.40	0.1	4.63	**1.34**	0.28	0.08
	3.45	Granivore (grain and seeds)	1.04	0.30	0.06	0.02	0.50	0.14	0.03	0.01
	3.45	Frugivore (fruit)	2.08	0.60	0.12	0.04	0.99	0.29	0.06	0.02
Medium Sized Bird (0.1 kg)										
Reproduction	3.45	Insectivore	5.24	**1.52**	0.31	0.1	3.62	**1.05**	0.22	0.06
	3.45	Granivore (grain and seeds)	0.81	0.23	0.05	0.01	0.39	0.11	0.02	0.01
	3.45	Frugivore (fruit)	1.62	0.47	0.10	0.03	0.77	0.22	0.05	0.01

Table 8 Expanded risk assessment of lambda-cyhalothrin for birds based on the succulent pea crops application rate (28.426 kg a.i./ha × 3 applications per season).

			Maximum nomogram residues				Mean nomogram residues			
			On-field		Off Field		On-field		Off Field	
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Small Bird (0.02 kg)										
Reproduction	3.45	Insectivore	4.62	**1.34**	0.28	0.1	3.19	0.92	0.19	0.06
	3.45	Granivore (grain and		0.21	0.04	0.01			0.02	0.01

		seeds)	0.71				0.34	0.10		
	3.45	Frugivore (fruit)	1.43	0.41	0.09	0.02	0.68	0.20	0.04	0.01
Medium Sized Bird (0.1 kg)										
Reproduction	3.45	Insectivore	3.60	**1.04**	0.22	0.1	2.49	0.72	0.15	0.04
	3.45	Granivore (grain and seeds)	0.56	0.16	0.03	0.01	0.27	0.08	0.02	0.005
	3.45	Frugivore (fruit)	1.11	0.32	0.07	0.02	0.53	0.15	0.03	0.01

Table 9 Expanded risk assessment of lambda-cyhalothrin for birds based on the crop subgroup 5A application rate (e.g., broccoli, cabbage brussel sprouts - 22.936 g a.i./ha × 3 applications per season).

			Maximum nomogram residues				**Mean nomogram residues**			
			On-field		**Off Field**		**On-field**		**Off Field**	
	Toxicity (mg a.i./kg bw/d)	**Food Guild (food item)**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**
Small Bird (0.02 kg)										
Reproduction	3.45	Insectivore	3.72	**1.08**	0.22	0.1	2.57	0.75	0.15	0.04
	3.45	Granivore (grain and seeds)	0.58	0.17	0.03	0.01	0.27	0.08	0.02	0.005
	3.45	Frugivore (fruit)	1.15	0.33	0.07	0.02	0.55	0.16	0.03	0.01

Table 10 Expanded level risk assessment of lambda-cyhalothrin for wild mammals based on the highest seasonal ground application, turf (4 × 37.0 g a.i./ha with a 7 day interval).

			Maximum nomogram residues				Mean nomogram residues			
			On-field		Off Field		On-field		Off Field	
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Small Mammal (0.015 kg)										
Acute	2.00	Insectivore	3.86	**1.93**	0.23	0.12	2.66	**1.33**	0.16	0.08
	2.00	Granivore (grain and seeds)	0.60	0.30	0.04	0.02	0.28	0.14	0.02	0.01
	2.00	Frugivore (fruit)	1.19	0.60	0.07	0.04	0.57	0.28	0.03	0.02
Reproduction	0.75	Insectivore	3.86	**5.15**	0.23	0.31	2.66	**3.55**	0.16	0.21
	0.75	Granivore (grain and seeds)	0.60	0.80	0.04	0.05	0.28	0.38	0.02	0.02
	0.75	Frugivore (fruit)	1.19	**1.59**	0.07	0.10	0.57	0.76	0.03	0.05
Medium Sized Mammal (0.035 kg)										
Acute	2.00	Insectivore	3.38	**1.69**	0.20	0.10	2.34	**1.17**	0.14	0.07
	2.00	Granivore (grain and seeds)	0.52	0.26	0.03	0.02	0.25	0.12	0.01	0.01
	2.00	Frugivore (fruit)	1.05	0.52	0.06	0.03	0.50	0.25	0.03	0.01
	2.00	Herbivore (short grass)	7.49	**3.74**	0.45	0.22	2.66	**1.33**	0.16	0.08
	2.00	Herbivore (long grass)	4.57	**2.29**	0.27	0.14	1.49	0.75	0.09	0.04
	2.00	Herbivore (forage crops)	6.93	**3.46**	0.42	0.21	2.29	**1.14**	0.14	0.07
Reproduction	0.75	Insectivore	3.38	**4.51**	0.20	0.27	2.34	**3.11**	0.14	0.19
	0.75	Granivore (grain and seeds)	0.52	0.70	0.03	0.04	0.25	0.33	0.01	0.02
	0.75	Frugivore (fruit)	1.05	**1.40**	0.06	0.08	0.50	0.67	0.03	0.04
	0.75	Herbivore (short grass)	7.49	**9.98**	0.45	0.60	2.66	**3.54**	0.16	0.21
	0.75	Herbivore (long grass)	4.57	**6.09**	0.27	0.37	1.49	**1.99**	0.09	0.12
	0.75	Herbivore (Broadleaf plants)	6.93	**9.23**	0.42	0.55	2.29	**3.05**	0.14	0.18

Large Sized Mammal (1 kg)										
Acute	2.00	Insectivore	1.81	0.90	0.11	0.05	1.25	0.62	0.07	0.04
	2.00	Granivore (grain and seeds)	0.28	0.14	0.02	0.01	0.13	0.07	0.01	0.004
	2.00	Frugivore (fruit)	0.56	0.28	0.03	0.02	0.27	0.13	0.02	0.01
	2.00	Herbivore (short grass)	4.00	**2.00**	0.24	0.12	1.42	0.71	0.09	0.04
	2.00	Herbivore (long grass)	2.44	**1.22**	0.15	0.07	0.80	0.40	0.05	0.02
	2.00	Herbivore (Broadleaf plants)	3.70	**1.85**	0.22	0.11	1.22	0.61	0.07	0.04
Reproduction	0.75	Insectivore	1.81	**2.41**	0.11	0.14	1.25	**1.66**	0.07	0.10
	0.75	Granivore (grain and seeds)	0.28	0.37	0.02	0.02	0.13	0.18	0.01	0.01
	0.75	Frugivore (fruit)	0.56	0.75	0.03	0.04	0.27	0.36	0.02	0.02
	0.75	Herbivore (short grass)	4.00	**5.33**	0.24	0.32	1.42	**1.89**	0.09	0.11
	0.75	Herbivore (long grass)	2.44	**3.26**	0.15	0.20	0.80	**1.06**	0.05	0.06
	0.75	Herbivore (Broadleaf plants)	3.70	**4.93**	0.22	0.30	1.22	**1.63**	0.07	0.10

Values in bold exceed Level of concern (≥ 1)

Table 11 Expanded level risk assessment of lambda-cyhalothrin for wild mammals based on the succulent pea crops application rate (28.426 kg a.i./ha × 3 applications per season).

			Maximum nomogram residues				**Mean nomogram residues**			
			On-field		**Off Field**		**On-field**		**Off Field**	
	Toxicity (mg a.i./kg bw/d)	**Food Guild (food item)**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**
Small Mammal (0.015 kg)										
Acute	2.00	Insectivore	2.65	**1.33**	0.16	0.08	1.83	0.92	0.11	0.05
	2.00	Granivore (grain and seeds)	0.41	0.21	0.02	0.01	0.20	0.10	0.01	0.01
	2.00	Frugivore (fruit)	0.82	0.41	0.05	0.02	0.39	0.20	0.02	0.01
Reproduction	0.75	Insectivore	2.65	**3.54**	0.16	0.21	1.83	**2.44**	0.11	0.15
	0.75	Granivore (grain and seeds)	0.41	0.55	0.02	0.03	0.20	0.26	0.01	0.02
	0.75	Frugivore (fruit)	0.82	**1.10**	0.05	0.07	0.39	0.52	0.02	0.03

Medium Sized Mammal (0.035 kg)										
Acute	2.00	Insectivore	2.33	**1.16**	0.14	0.07	1.61	0.80	0.10	0.05
	2.00	Granivore (grain and seeds)	0.36	0.18	0.02	0.01	0.17	0.09	0.01	0.01
	2.00	Frugivore (fruit)	0.72	0.36	0.04	0.02	0.34	0.17	0.02	0.01
	2.00	Herbivore (short grass)	5.15	**2.57**	0.31	0.15	1.83	0.91	0.11	0.05
	2.00	Herbivore (long grass)	3.14	**1.57**	0.19	0.09	1.03	0.51	0.06	0.03
	2.00	Herbivore (forage crops)	4.76	**2.38**	0.29	0.14	1.57	0.79	0.09	0.05
Reproduction	0.75	Insectivore	2.33	**3.10**	0.14	0.19	1.61	**2.14**	0.10	0.13
	0.75	Granivore (grain and seeds)	0.36	0.48	0.02	0.03	0.17	0.23	0.01	0.01
	0.75	Frugivore (fruit)	0.72	0.96	0.04	0.06	0.34	0.46	0.02	0.03
	0.75	Herbivore (short grass)	5.15	**6.86**	0.31	0.41	1.83	**2.44**	0.11	0.15
	0.75	Herbivore (long grass)	3.14	**4.19**	0.19	0.25	1.03	**1.37**	0.06	0.08
	0.75	Herbivore (Broadleaf plants)	4.76	**6.35**	0.29	0.38	1.57	**2.10**	0.09	0.13
Large Sized Mammal (1 kg)										
Acute	2.00	Insectivore	1.24	0.62	0.07	0.04	0.86	0.43	0.05	0.03
	2.00	Granivore (grain and seeds)	0.19	0.1	0.01	0.01	0.09	0.05	0.01	0.003
	2.00	Frugivore (fruit)	0.38	0.19	0.02	0.01	0.18	0.09	0.01	0.01
	2.00	Herbivore (short grass)	2.75	**1.38**	0.17	0.08	0.98	0.49	0.06	0.03
	2.00	Herbivore (long grass)	1.68	0.84	0.10	0.05	0.55	0.27	0.03	0.02
	2.00	Herbivore (Broadleaf plants)	2.55	**1.27**	0.15	0.08	0.84	0.42	0.05	0.03
Reproduction	0.75	Insectivore	1.24	**1.66**	0.07	0.10	0.86	**1.14**	0.05	0.07
	0.75	Granivore (grain and seeds)	0.19	0.26	0.01	0.02	0.09	0.12	0.01	0.01
	0.75	Frugivore (fruit)	0.38	0.51	0.02	0.03	0.18	0.24	0.01	0.01
	0.75	Herbivore (short grass)	2.75	**3.67**	0.17	0.22	0.98	**1.30**	0.06	0.08
	0.75	Herbivore (long grass)	1.68	**2.24**	0.10	0.13	0.55	0.73	0.03	0.04
	0.75	Herbivore (Broadleaf plants)	2.55	**3.39**	0.15	0.20	0.84	**1.12**	0.05	0.07

Table 12 Expanded level risk assessment of lambda-cyhalothrin for wild mammals based on the crop subgroup 5A application rate (e.g., broccoli, cabbage brussel sprouts - 22.936 g a.i./ha × 3 applications per season).

			Maximum nomogram residues				Mean nomogram residues			
			On-field		Off Field		On-field		Off Field	
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Small Mammal (0.015 kg)										
Acute	2.00	Insectivore	2.14	**1.07**	0.13	0.06	1.48	0.74	0.09	0.04
	2.00	Granivore (grain and seeds)	0.33	0.17	0.02	0.01	0.16	0.08	0.01	0.005
	2.00	Frugivore (fruit)	0.66	0.33	0.04	0.02	0.32	0.16	0.02	0.01
Reproduction	0.75	Insectivore	2.14	**2.86**	0.13	0.17	1.48	**1.97**	0.09	0.12
	0.75	Granivore (grain and seeds)	0.33	0.44	0.02	0.03	0.16	0.21	0.01	0.01
	0.75	Frugivore (fruit)	0.66	0.88	0.04	0.05	0.32	0.42	0.02	0.03
Medium Sized Mammal (0.035 kg)										
Acute	2.00	Insectivore	1.88	0.94	0.11	0.06	1.30	0.65	0.08	0.04
	2.00	Granivore (grain and seeds)	0.29	0.14	0.02	0.01	0.14	0.07	0.01	0.004
	2.00	Frugivore (fruit)	0.58	0.29	0.03	0.02	0.28	0.14	0.02	0.01
	2.00	Herbivore (short grass)	4.15	**2.08**	0.25	0.12	1.48	0.74	0.09	0.04
	2.00	Herbivore (long grass)	2.54	**1.27**	0.15	0.08	0.83	0.41	0.05	0.02
	2.00	Herbivore (forage crops)	3.84	**1.92**	0.23	0.12	1.27	0.64	0.08	0.04
Reproduction	0.75	Insectivore	1.88	**2.50**	0.11	0.15	1.30	**1.73**	0.08	0.10
	0.75	Granivore (grain and seeds)	0.29	0.39	0.02	0.02	0.14	0.18	0.01	0.01
	0.75	Frugivore (fruit)	0.58	0.77	0.03	0.05	0.28	0.37	0.02	0.02
	0.75	Herbivore (short grass)	4.15	**5.54**	0.25	0.33	1.48	**1.97**	0.09	0.12
	0.75	Herbivore (long grass)	2.54	**3.38**	0.15	0.20	0.83	**1.10**	0.05	0.07
	0.75	Herbivore (Broadleaf plants)	3.84	**5.12**	0.23	0.31	1.27	**1.69**	0.08	0.10
Large Sized Mammal (1 kg)										
Acute	2.00	Insectivore	1.00	0.50	0.06	0.03	0.69	0.35	0.04	0.02
	2.00	Granivore (grain and seeds)	0.16	0.08	0.01	0.005	0.07	0.04	0.004	0.002
	2.00	Frugivore (fruit)	0.31	0.16	0.02	0.01	0.15	0.07	0.01	0.004

	2.00	Herbivore (short grass)	2.22	**1.11**	0.13	0.07	0.79	0.39	0.05	0.02
	2.00	Herbivore (long grass)	1.36	0.68	0.08	0.04	0.44	0.22	0.03	0.01
	2.00	Herbivore (Broadleaf plants)	2.05	**1.03**	0.12	0.06	0.68	0.34	0.04	0.02
Reproduction	0.75	Insectivore	1.00	**1.34**	0.06	0.08	0.69	0.92	0.04	0.06
	0.75	Granivore (grain and seeds)	0.16	0.21	0.01	0.01	0.07	0.10	0.004	0.01
	0.75	Frugivore (fruit)	0.31	0.41	0.02	0.02	0.15	0.20	0.01	0.01
	0.75	Herbivore (short grass)	2.22	**2.96**	0.13	0.18	0.79	**1.05**	0.05	0.06
	0.75	Herbivore (long grass)	1.36	**1.81**	0.08	0.11	0.44	0.59	0.03	0.04
	0.75	Herbivore (Broadleaf plants)	2.05	**2.74**	0.12	0.16	0.68	0.91	0.04	0.05

Table 13 Expanded level risk assessment of lambda-cyhalothrin for wild mammals based on the strawberry application rate (12.48 g a.i./ha × 3 applications per season)

			Maximum nomogram residues				Mean nomogram residues			
			On-field		Off Field		On-field		Off Field	
	Toxicity (mg a.i./kg bw/d)	**Food Guild (food item)**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**
Small Mammal (0.015 kg)										
Reproduction	0.75	Insectivore	1.17	**1.55**	0.07	0.09	0.80	**1.07**	0.05	0.06
	0.75	Granivore (grain and seeds)	0.18	0.24	0.01	0.01	0.09	0.11	0.01	0.01
	0.75	Frugivore (fruit)	0.36	0.48	0.02	0.03	0.17	0.23	0.01	0.01
Medium Sized Mammal (0.035 kg)										
Acute	2.00	Insectivore	1.02	0.51	0.06	0.03	0.71	0.35	0.04	0.02
	2.00	Granivore (grain and seeds)	0.16	0.08	0.01	0.005	0.08	0.04	0.005	0.002
	2.00	Frugivore (fruit)	0.32	0.16	0.02	0.01	0.15	0.08	0.01	0.005
	2.00	Herbivore (short grass)	2.26	**1.13**	0.14	0.07	0.80	0.40	0.05	0.02
	2.00	Herbivore (long grass)	1.38	0.69	0.08	0.04	0.45	0.23	0.03	0.01
	2.00	Herbivore (forage crops)	2.09	**1.05**	0.13	0.06	0.69	0.35	0.04	0.02
Reproduction	0.75	Insectivore	1.02	**1.36**	0.06	0.08	0.71	0.94	0.04	0.06
	0.75	Granivore (grain and seeds)	0.16	0.21	0.01	0.01	0.08	0.10	0.005	0.01

	0.75	Frugivore (fruit)	0.32	0.42	0.02	0.03	0.15	0.20	0.01	0.01
	0.75	Herbivore (short grass)	2.26	**3.01**	0.14	0.18	0.80	**1.07**	0.05	0.06
	0.75	Herbivore (long grass)	1.38	**1.84**	0.08	0.11	0.45	0.60	0.03	0.04
	0.75	Herbivore (Broadleaf plants)	2.09	**2.79**	0.13	0.17	0.69	0.92	0.04	0.06
Large Sized Mammal (1 kg)										
Reproduction	0.75	Insectivore	0.55	0.73	0.03	0.04	0.38	0.50	0.02	0.03
	0.75	Granivore (grain and seeds)	0.08	0.11	0.01	0.01	0.04	0.05	0.002	0.003
	0.75	Frugivore (fruit)	0.17	0.23	0.01	0.01	0.08	0.11	0.005	0.01
	0.75	Herbivore (short grass)	1.21	**1.61**	0.07	0.10	0.43	0.57	0.03	0.03
	0.75	Herbivore (long grass)	0.74	0.98	0.04	0.06	0.24	0.32	0.01	0.02
	0.75	Herbivore (Broadleaf plants)	1.12	**1.49**	0.07	0.09	0.37	0.49	0.02	0.03

Table 14 Expanded level risk assessment of lambda-cyhalothrin for wild mammals based on the maximum early airblast application rate (various fruit crops - 12.688 g a.i./ha × 3 applications per season)

			Maximum nomogram residues				**Mean nomogram residues**			
			On-field		**Off Field**		**On-field**		**Off Field**	
	Toxicity (mg a.i./kg bw/d)	**Food Guild (food item)**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**
Small Mammal (0.015 kg)										
1.18	**1.58**	0.88	**1.17**	0.82	**1.09**	0.61	0.81			
0.18	0.24	0.14	0.18	0.09	0.12	0.06	0.09			
0.37	0.49	0.27	0.36	0.17	0.23	0.13	0.17			
Medium Sized Mammal (0.035 kg)										
Acute	2.00	Insectivore	1.04	0.52	0.77	0.38	0.72	0.36	0.53	0.27
	2.00	Granivore (grain and seeds)	0.16	0.08	0.12	0.06	0.08	0.04	0.06	0.03
	2.00	Frugivore (fruit)	0.32	0.16	0.24	0.12	0.15	0.08	0.11	0.06
	2.00	Herbivore (short grass)	2.30	**1.15**	1.70	0.85	0.82	0.41	0.60	0.30
	2.00	Herbivore (long grass)	1.40	0.70	1.04	0.52	0.46	0.23	0.34	0.17
	2.00	Herbivore (forage crops)	2.13	**1.06**	1.57	0.79	0.70	0.35	0.52	0.26

Reproduction	0.75	Insectivore	1.04	**1.38**	0.77	**1.02**	0.72	0.96	0.53	0.71
	0.75	Granivore (grain and seeds)	0.16	0.21	0.12	0.16	0.08	0.10	0.06	0.08
	0.75	Frugivore (fruit)	0.32	0.43	0.24	0.32	0.15	0.20	0.11	0.15
	0.75	Herbivore (short grass)	2.30	**3.06**	1.70	**2.27**	0.82	**1.09**	0.60	0.81
	0.75	Herbivore (long grass)	1.40	**1.87**	1.04	**1.38**	0.46	0.61	0.34	0.45
	0.75	Herbivore (Broadleaf plants)	2.13	**2.83**	1.57	**2.10**	0.70	0.94	0.52	0.69
Large Sized Mammal (1 kg)										
Reproduction	0.75	Insectivore	0.55	0.74	0.41	0.55	0.38	0.51	0.28	0.38
	0.75	Granivore (grain and seeds)	0.09	0.11	0.06	0.08	0.04	0.05	0.03	0.04
	0.75	Frugivore (fruit)	0.17	0.23	0.13	0.17	0.08	0.11	0.06	0.08
	0.75	Herbivore (short grass)	1.23	**1.64**	0.91	**1.21**	0.44	0.58	0.32	0.43
	0.75	Herbivore (long grass)	0.75	**1.00**	0.55	0.74	0.24	0.33	0.18	0.24
	0.75	Herbivore (Broadleaf plants)	1.14	**1.51**	0.84	**1.12**	0.38	0.50	0.28	0.37

Table 15 Expanded level risk assessment of lambda-cyhalothrin for wild mammals based on the maximum late airblast application rate (various fruit crops - 12.688 g a.i./ha × 3 applications per season)

			Maximum nomogram residues				**Mean nomogram residues**			
			On-field		**Off Field**		**On-field**		**Off Field**	
	Toxicity (mg a.i./kg bw/d)	**Food Guild (food item)**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**
Small Mammal (0.015 kg)										
Reproduction	0.75	Insectivore	1.18	**1.58**	0.70	0.93	0.82	**1.09**	0.48	0.64
	0.75	Granivore (grain and seeds)	0.18	0.24	0.11	0.14	0.09	0.12	0.05	0.07
	0.75	Frugivore (fruit)	0.37	0.49	0.22	0.29	0.17	0.23	0.10	0.14
Medium Sized Mammal (0.035 kg)										
Acute	2.00	Insectivore	1.04	0.52	0.61	0.31	0.72	0.36	0.42	0.21
	2.00	Granivore (grain and seeds)	0.16	0.08	0.09	0.05	0.08	0.04	0.05	0.02
	2.00	Frugivore (fruit)	0.32	0.16	0.19	0.09	0.15	0.08	0.09	0.05
	2.00	Herbivore (short grass)	2.30	**1.15**	1.36	0.68	0.82	0.41	0.48	0.24

	2.00	Herbivore (long grass)	1.40	0.70	0.83	0.41	0.46	0.23	0.27	0.14
	2.00	Herbivore (forage crops)	2.13	**1.06**	1.25	0.63	0.70	0.35	0.41	0.21
Reproduction	0.75	Insectivore	1.04	**1.38**	0.61	0.82	0.72	0.96	0.42	0.56
	0.75	Granivore (grain and seeds)	0.16	0.21	0.09	0.13	0.08	0.10	0.05	0.06
	0.75	Frugivore (fruit)	0.32	0.43	0.19	0.25	0.15	0.20	0.09	0.12
	0.75	Herbivore (short grass)	2.30	**3.06**	1.36	**1.81**	0.82	**1.09**	0.48	0.64
	0.75	Herbivore (long grass)	1.40	**1.87**	0.83	**1.10**	0.46	0.61	0.27	0.36
	0.75	Herbivore (Broadleaf plants)	2.13	**2.83**	1.25	**1.67**	0.70	0.94	0.41	0.55
Large Sized Mammal (1 kg)										
Reproduction	0.75	Insectivore	0.55	0.74	0.33	0.44	0.38	0.51	0.23	0.30
	0.75	Granivore (grain and seeds)	0.09	0.11	0.05	0.07	0.04	0.05	0.02	0.03
	0.75	Frugivore (fruit)	0.17	0.23	0.10	0.14	0.08	0.11	0.05	0.06
	0.75	Herbivore (short grass)	1.23	**1.64**	0.72	0.97	0.44	0.58	0.26	0.34
	0.75	Herbivore (long grass)	0.75	**1.00**	0.44	0.59	0.24	0.33	0.14	0.19
	0.75	Herbivore (Broadleaf plants)	1.14	**1.51**	0.67	0.89	0.38	0.50	0.22	0.30

Table 16 Expanded level risk assessment of lambda-cyhalothrin for wild mammals based on the maximum aerial application rate (soybean - 19.08 g a.i./ha × 3 applications per season)

			Maximum nomogram residues				**Mean nomogram residues**			
			On-field		**Off Field**		**On-field**		**Off Field**	
	Toxicity (mg a.i./kg bw/d)	**Food Guild (food item)**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**
Small Mammal (0.015 kg)										
Reproduction	0.75	Insectivore	1.78	**2.38**	0.41	0.55	1.23	**1.64**	0.28	0.38
	0.75	Granivore (grain and seeds)	0.28	0.37	0.06	0.08	0.13	0.18	0.03	0.04
	0.75	Frugivore (fruit)	0.55	0.74	0.13	0.17	0.26	0.35	0.06	0.08
Medium Sized Mammal (0.035 kg)										
Acute	2.00	Insectivore	1.56	0.78	0.36	0.18	1.08	0.54	0.25	0.12
	2.00	Granivore (grain and seeds)	0.24	0.12	0.06	0.03	0.12	0.06	0.03	0.01

	2.00	Frugivore (fruit)	0.48	0.24	0.11	0.06	0.23	0.12	0.05	0.03
	2.00	Herbivore (short grass)	3.46	**1.73**	0.79	0.40	1.23	0.61	0.28	0.14
	2.00	Herbivore (long grass)	2.11	**1.05**	0.49	0.24	0.69	0.34	0.16	0.08
	2.00	Herbivore (forage crops)	3.20	**1.60**	0.74	0.37	1.06	0.53	0.24	0.12
Reproduction	0.75	Insectivore	1.56	**2.08**	0.36	0.48	1.08	**1.44**	0.25	0.33
	0.75	Granivore (grain and seeds)	0.24	0.32	0.06	0.07	0.12	0.15	0.03	0.04
	0.75	Frugivore (fruit)	0.48	0.64	0.11	0.15	0.23	0.31	0.05	0.07
	0.75	Herbivore (short grass)	3.46	**4.61**	0.79	**1.06**	1.23	**1.64**	0.28	0.38
	0.75	Herbivore (long grass)	2.11	**2.81**	0.49	0.65	0.69	0.92	0.16	0.21
	0.75	Herbivore (Broadleaf plants)	3.20	**4.26**	0.74	0.98	1.06	**1.41**	0.24	0.32
Large Sized Mammal (1 kg)										
Reproduction	0.75	Insectivore	0.83	**1.11**	0.19	0.26	0.58	0.77	0.13	0.18
	0.75	Granivore (grain and seeds)	0.13	0.17	0.03	0.04	0.06	0.08	0.01	0.02
	0.75	Frugivore (fruit)	0.26	0.34	0.06	0.08	0.12	0.16	0.03	0.04
	0.75	Herbivore (short grass)	1.85	**2.46**	0.42	0.57	0.66	0.87	0.15	0.20
	0.75	Herbivore (long grass)	1.13	**1.50**	0.26	0.35	0.37	0.49	0.08	0.11
	0.75	Herbivore (Broadleaf plants)	1.71	**2.28**	0.39	0.52	0.56	0.75	0.13	0.17

Table 17 Effects on aquatic organisms

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	PMRA#
Freshwater species					
Daphnia magna	24h-Acute	Technical	EC50=3.78 µg/L EC50=6.72 µg/L	Very highly toxic	1249005 1249009 2635522
	48h-Acute		EC50=0.57 µg/L EC50=0.23 µg/L		1249005 1249009 2635522
	21d-life cycle		NOEC=0.0025 µg/L(number of young per female) NOEC=0.00198 µg/L (reproduction)		1204007 2635522
Daphnia pulex	48 hr-Acute	Transformation product Ia	EC50=105 000 µg/L	Practically non-toxic	2552956 2635522 2235707
Daphnia magna		Transformation product II	EC50>14.3 µg/L	Toxicity cannot be characterized but less toxic than the parent	
		Transformation product V	EC50=85 000 µg/L	Slightly toxic	
		Transformation product XV	EC50=0.16 µg/L	Very highly toxic	

Gammarus pulex	Dechlorinated tap water, flow through				
	24h-Acute	Technical	EC50=0.010 µg/L (normal swimming) LC_{50}=0.665 µg/L	Very highly toxic	2235714 2235712 2635522
	48h-Acute		EC50= 0.008 µg/L LC_{50}= 0.071 µg/L		
	72h-Acute		EC50= 0.0064 µg/L LC50= 0.031 µg/L		
	96h-Acute		EC50= 0.0059 µg/L LC50= 0.013 µg/L		
Arthropods	48-h Acute, static	Technical	Based on nominal concentrations:	Very highly toxic	2235716 2635522
Hyalella azteca			EC50=0.0023 µg/L		
Chaoborus sp			EC50=0.0028 µg/L		
Gammarus pulex			EC50=0.014 µg/L		
Asellus aquaticus			EC50=0.026 µg/L		
Corixa sp.			EC50=0.030 µg/L		
Cleon dipterium			EC50=0.038 µg/L		
Hydracarina			EC50=0.047 µg/L		

Ischnura elegans *Cyclops* sp . Ostracoda			EC50=0.130 µg/L EC50=0.300 µg/L EC50=3.3 µg/L		
Rainbow trout *(Oncorhynchus mykiss)*	96h-Acute	Technical	LC_{50}=0.24 µg/L LC_{50}=0.44 µg/L	Very highly toxic	1249006 2635522 2552956 1190914
	96h-Acute	Transformationm product Ia	LC_{50}>10800 µg/L	Slightly toxicToxicity cannot be characterized but less toxic than the parent	2552956 2635522 2235720 2552956
		Transformationm product V	LC_{50}=13300 µg/L	Slightly toxic	
		Transformationm product XV	LC_{50}=0.84 µg/L	Very highly toxic	
		Transformation product II	LC_{50} >18.7 µg/L	Toxicity cannot be characterized but less toxic than the parent.	

Bluegill sunfish *(Lepomis macrochirus)*	96h-Acute	Technical	LC_{50}=0.21 µg/L	Very highly toxic	1249007 2635522
	96h-Acute	Transformation product Ia	LC_{50}>14 000µg/L	Slightly toxic Toxicity cannot be characterized but less toxic than the parent	2552956 2635522
		Transformation product V	LC_{50}=36300 µg/L	Slightly toxic	
Fathead minnow *(Pimephales promelas)*	96h-Acute	Technical	LC_{50}=0.7 µg/L	Very highly toxic	2552956 2635522
	300d-Chronic (full life cycle)		NOEC=0.031 µg/L (survival of F1 generation larvae to 56days post-hatch)		1190838 2635522
	24h-Acute	Transformation product IV	LC_{50} = 60 µg/L	Very highly toxic	2635522 2552956
Three-spined stickleback	96 hour-Acute	Technical	LC_{50}=0.4 µg/L	Very highly toxic	2235722
Channel catfish	96 hour-Acute	Technical	LC_{50}=0.16 µg/L	Very highly toxic	2235723
Freshwater alga (*Selenastrum capricornutum*)	96h-Acute	Technical	E_rC50=5 µg/L E_yC50=5 µg/L		1249011 2635522
Vascular plant	Dissolved		No data available		
	Over-spray		No data available		

Sediment dwelling organisms					
Chironomus riparius	48-h Acute	Technical	EC50=1.5 µg/L	Very highly toxic	2635522
	28 d, water-sediment system, spiked sediment		NOEC=105 µg/kg sediment (emergence) (10.5 µg/kg, as determined by RMS review applying a factor of 10 to account for potential underestimation of toxicity due to exposure routes not considered, such as ingestion of contaminated food)		2635522 2235717
	28 d, water-sediment system, spiked overlying water		NOEC=0.049 µg/L sediment (emergence), and 0.013 µg/L (development) (as determined by RMS review applying a factor of 10 to account for potential underestimation of toxicity due to exposure routes not considered, such as ingestion of contaminated food)		2635522 2235717
	28 d	Transformation product Ia	NOEC=20800 µg/L (emergence and development; based on initial measured concentrations in the aqueous layer)		2552956 2635522
		Transformation product VI	NOEC=11 000 µg/L (emergence) NOEC=19500 µg/L (development; based on initial measured concentrations in the aqueous layer)		
		Transformation product	NOEC=0.58 mg/kg (emergence		

		XV	and development based on initial measured concentrations in the sediment)		
Marine species					
Crustacean Mysid shrimp *(Mysidopsis bahia)*	24h-Acute 48h-Acute 72h-Acute 96h-Acute	Technical	LC_{50}>0.017 µg a.i./L LC_{50}=0.0075 µg a.i./L LC_{50}=0.0049 µg a.i./L LC_{50}=0.0041 µg a.i./L	Very highly toxic	1249012
	28d-Chronic		NOEC=0.00022 µg a.i./L (number of offspring per available female reproductive days)		1218901 2635522
Mollusk Pacific oyster *(Crassostrea gigas)*	48h-Acute	Technical	No valid data available		
	Chronic		No data available		
Sheepshead minnow *(Cyprinodon variegatus)*	24h-Acute 48h-Acute 72h-Acute 96h-Acute	Technical	LC_{50}= 1.34 µg a.i./L LC_{50}= 1.14 µg a.i./L LC_{50}= 0.85 µg a.i./L LC_{50}= 0.81 µg a.i./L	Very highly toxic	2235724
	Early life stage	Technical	NOEC=0.25 µg a.i./L (larvae weight)		2235725 2635522 2552956
Salmonid	Acute		No data available		
Marine alga	96h-Acute		No data available		

[a] USEPA classification, where applicable

Table 18 Refined Risk Assessment for Aquatic Organisms (Off-field, spray drift) using lowest rates

Organism	Exposure	Endpoint value[1]	Lowest Application rate	EEC µg a.i./L	RQ			
					6%	23 %	59 %	74%
Freshwater Species								
Invertebrates	Acute	HC_5 from SSD (0.00139 µg a.i./L)	5.04 g a.i./ha (ground boom)	0.04	**29**	**NA**	**NA**	NA
			6.96 g a.i./ha (airblast)	0.5 (59%), 0.6 (74%)	**NA**	**NA**	**360**	**432**
			9.96 g a.i./ha (aerial)	0.3	**NA**	**216**	**NA**	**NA**
Waterflea (*Daphnia magna*)	Chronic	21-day NOEC = 0.00198 µg a.i./L	5.04 g a.i./ha	0.04	**19**	**NA**	**NA**	**NA**
			6.96 g a.i./ha	0.5/0.6	**NA**	**NA**	**253**	**303**
			9.96 g a.i./ha	0.3	**NA**	**60**	**NA**	**NA**
Fish	Acute	HC_5=0.113 µg a.i./L	5.04 g a.i./ha	0.04	0.4	**NA**	**NA**	**NA**
			6.96 g a.i./ha	0.5/0.6	**NA**	**NA**	**4.5**	**5.3**
			9.96 g a.i./ha	0.3	**NA**	**2.7**	**NA**	**NA**
Fathead minnow	Chronic	30 d NOEC = 0.031 µg a.i./L	5.04 g a.i./ha	0.04	**1.2**	**NA**	**NA**	**NA**
			6.96 g a.i./ha	0.5/0.6	**NA**	**NA**	**16**	**19**
			9.96 g a.i./ha	0.3	**NA**	**9.7**	**NA**	**NA**
Aquatic plant	No data available							
Algae (*Selenastrum capricornutum*)	Acute	72-h EC50 = 2.5 µg a.i./L	5.04 g a.i./ha	0.04	0.02	**NA**	**NA**	**NA**
			6.96 g a.i./ha	0.5/0.6	**NA**	**NA**	0.2	0.24
			9.96 g a.i./ha	0.3	**NA**	0.12	**NA**	**NA**
Amphibians[2]	Acute	0.113 µg a.i./L	5.04 g a.i./ha	0.2	**1.8**	**NA**	**NA**	**NA**
			6.96 g a.i./ha	2.7(59%) 3.4(74%)	**NA**	**NA**	**24**	**30**
			9.96 g a.i./ha	1.5	**NA**	**46**	**NA**	**NA**
Amphibians[2]	Chronic	30 d NOEC= 0.031 µg a.i./L	5.04 g a.i./ha	0.2	**6.5**	**NA**	**NA**	**NA**
			6.96 g a.i./ha	2.7(59%) 3.4(74%	**NA**	**NA**	**87**	**110**
			9.96 g a.i./ha	1.5	**NA**	**48**	**NA**	**NA**

Marine/Estuarine Species								
Invertebrates Mysid shrimp (*Mysidopsis bahia*)	Acute	24-h LC_{50} =0.0021 µg a.i./L)	5.04 g a.i./ha	0.04	**18**	**NA**	**NA**	**NA**
			6.96 g a.i./ha	0.5/0.6	**NA**	**NA**	**24**	**286**
			9.96 g a.i./ha	0.3	**NA**	**143**	**NA**	**NA**
	Chronic	28 d NOAEC = 0.00022 µg a.i./L	5.04 g a.i./ha	0.04	**172**	**NA**	**NA**	**NA**
			6.96 g a.i./ha	0.5/0.6	**NA**	**NA**	**2273**	**2727**
			9.96 g a.i./ha	0.3	**NA**	**1364**	**NA**	**NA**
Fish (*Cyprinodon variegates*)	Acute	24-h LC_{50} = 0.081 µg a.i./L	5.04 g a.i./ha	0.04	0.47	**NA**	**NA**	**NA**
			6.96 g a.i./ha	0.5/0.6	**NA**	**NA**	**6.2**	**7.4**
			9.96 g a.i./ha	0.3	**NA**	**3.7**	**NA**	**NA**
Algae	No data available							

[1] Endpoints were divided by an Uncertainty Factor to account for varying protection goals (i.e., protection at the community, population, or individual level)
[2] Endpoints from fish used as surrogate
Values in bold exceed Level of concern (≥ 1)

Table 19 Refined Risk Assessment for Aquatic Organisms (Off-field, spray drift) using highest rates

Organism	Exposure	Endpoint value[1]	Lowest Application rate	EEC µg a.i./L	RQ			
					6%	26 %	59 %	74%
Freshwater Species								
Fish	Acute	HC_5=0.113 µg a.i./L	37 g a.i./ha × 4 (ground boom)	0.9	**8.0**	**NA**	**NA**	**NA**
			12.688 g a.i./ha × 3 (airblast)	2.5 (59%) 3.1 (74%)	NA	**NA**	**22**	**27**
			19.08 g a.i./ha × 3 (aerial)	1.4	**NA**	**12**	**NA**	**NA**
Algae (*Selenastrum capricornutum*)	Acute	72-h EC50 = 2.5 µg a.i./L	37 g a.i./ha × 4 (ground boom)	0.9	0.4	**NA**	**NA**	**NA**
			12.688 g a.i./ha × 3 (airblast)	2.5 (59%) 3.1 (74%)	NA	**NA**	1	**1.2**
			19.08 g a.i./ha × 3 (aerial)	1.4	**NA**	0.6	**NA**	**NA**

Marine/Estuarine Species								
Fish (*Cyprinodon variegates*)	Acute	24-h LC_{50} = 0.081 µg a.i./L	37 g a.i./ha × 4 (ground boom)	0.9	**11**	**NA**	**NA**	**NA**
			12.688 g a.i./ha × 3 (airblast)	2.5 (59%) 3.1(74%)	**NA**	**NA**	**31**	**38**
			19.08 g a.i./ha × 3 (aerial)	1.4	**NA**	**17**	**NA**	**NA**

[1] Endpoints were divided by an Uncertainty Factor to account for varying protection goals (i.e., protection at the community, population, or individual level)
[2] Endpoints from fish used as surrogate
Values in bold exceed Level of concern (≥ 1)

Table 20 PRZM/EXAMS runoff modelling results (µg a.i./L) for lambda-cyhalothrin in water bodies 0.8 m and 0.15 m deep, excluding spray drift.

Depth of water body	Peak	96-hour	21-day	60-day	90-day	Yearly
Turf						
15 cm	5.7	0.085	0.033	0.026	0.022	0.015
80 cm	1.1	0.084	0.032	0.025	0.022	0.014
soybean						
15 cm	6.0	0.091	0.046	0.035	0.032	0.025
80 cm	1.1	0.090	0.045	0.035	0.032	0.024
tobacco						
15 cm	0.18	0.0028	0.0013	0.0011	0.0011	0.0008
80 cm	0.033	0.0028	0.0013	0.0011	0.0011	0.0008

Table 21 Refined Risk Assessment for Aquatic Organisms (Runoff)

Organism	Endpoint value[1]	Scenario	EEC (µg a.i./L)[2]	RQ	LOC Exceeded
Freshwater Species					
Invertebrates	Acute HC5 from SSD (0.00139 µg a.i./L)	Turf	1.1	**791**	**Yes**
		Soybean	1.1	**791**	**Yes**
		Tobacco	0.033	**24**	**Yes**
Waterflea (*Daphnia magna*)	Chronic 21-day NOEC = 0.00198 µg a.i./L	Turf	0.032	**162**	**Yes**
		Soybean	0.045	**22.7**	**Yes**
		Tobacco	0.0013	0.7	No
Fish	HC_5 from SSD = 0.113 µg a.i./L	Turf	0.084	0.7	No
		Soybean	0.09	0.8	No
		Tobacco	0.0028	0.02	No
Fathead minnow (*Pimephales promelas*)	Chronic 30 d NOEC = 0.031 µg a.i./L	Turf	0.032	**1**	**Yes**
		Soybean	0.045	**1.45**	**Yes**
		Tobacco	0.0013	0.04	No
Aquatic plant	No data available				
Algae (*Selenastrum capricornutum*)	Acute 72-h EC50= 2.5 µg a.i./L)	Turf	1.1	0.4	No
		Soybean	1.1	0.4	No
		Tobacco	0.033	0.01	No
Amphibians[3]	Acute 0.113 µg a.i./L	Turf	0.085	0.8	No
		Soybean	0.091	0.8	No
		Tobacco	0.0028	0.02	No
Amphibians[3]	Chronic 30-d NOEC = (0.031 µg a.i./L)	Turf	0.033	**1**	**Yes**
		Soybean	0.046	**1.48**	**Yes**
		Tobacco	0.0013	0.04	No
Marine Species					
Estuarine/marine Invertebrates Mysid shrimp (*Mysidopsis*	Acute 24-h LC_{50}=0.00205 µg a.i./L	Turf	1.1	**537**	**Yes**
		Soybean	1.1	**537**	**Yes**
		Tobacco	0.033	**16**	**Yes**
	Chronic	Turf	0.032	**145**	**Yes**

bahia)	28-d NOAEC= (0.00022 µg a.i./L)	Soybean	0.046	**209**	**Yes**
		Tobacco	0.0013	**5.9**	**Yes**
Fish (*Cyprinodon variegates*)	Acute 96-h LC_{50} = 0.081 µg a.i./L	Turf	0.084	**1.0**	**Yes**
		Soybean	0.09	**1.1**	**Yes**
		Tobacco	0.0028	0.03	No
Algae	No data available				

[1] Endpoints were divided by an Uncertainty Factor to account for varying protection goals (i.e., protection at the community, population, or individual level)
[2] EEC based on a 15 cm water body depth for amphibians and a 80 cm water depth for all other aquatic organisms.
[3] Endpoints from fish used as surrogate

Table 22 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Lambda-cyhalothrin Are criteria met?
CEPA toxic or CEPA toxic equivalent[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		Yes
Persistence[3]:	Soil	Half-life ≥ 182 days	Yes: 7.2->1000 days
	Water	Half-life ≥ 182 days	No: 0.28 days
	Whole system (Water + Sediment)	Half-life ≥ 365 days	No: 12.6 – 60 days (80th percentile of the mean = 35.4 d)
	Air	Half-life ≥ 2 days or evidence of long range transport	Volatilization is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure (2×10^{-4} mPa) and Henry's Law Constant (1.8×10^{-7} atm m^3/mole).
Bioaccumulation[4]	Log $K_{OW} \geq 5$		Yes: 7
	BCF ≥ 5000		1500-6691
	BAF ≥ 5000		Not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			**No, does not meet all TSMP Track 1 criteria.**

[1] All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (i.e., all other TSMP criteria are met).

[2] The policy considers a substance "predominantly anthropogenic" if, based on expert judgment, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

[4] The log K_{OW} and/or BCF and/or BAF are preferred over log K_{OW}.

Appendix XIII Monitoring Data

Water Monitoring Data

A search for water monitoring data on cyhalothrin and lambda-cyhalothrin in Canadian and American water bodies was undertaken. Few Canadian studies were available for estimation of total cyhalothrin or lambda-cyhalothrin residues in water bodies. Monitoring data were available from Quebec, Nova Scotia, New Brunswick, Prince Edward Island, British Columbia and across the United States.

For the purposes of the water assessment, information extracted from the available sources was summarized by water type. Groundwater, finished/treated water and ambient surface water bodies such as rivers, lakes and reservoirs are considered potential sources of drinking water and thus relevant for use in the dietary risk assessment for human health. The ambient surface water sources mentioned above, in addition to water bodies which are not considered drinking water sources for humans like ponds, ditches and runoff, are considered relevant for aquatic risk assessment purposes.

Summary of Water Monitoring Results

In general, sampling occurred in use areas and during the summer months when lambda-cyhalothrin would be applied. Based on available monitoring data, lambda-cyhalothrin is seldom detected in water across Canada and US.

Groundwater Sources
(PMRA 1311119, 1311120, 1403269, 2170936, 2312780, 2505827, 2505828 and 2589776)

A total of 7,606 ground water samples were analyzed for cyhalothrin residues in Canada and the US. Considering Canadian data only, 491 groundwater samples were analyzed.

There were no detections of cyhalothrin residues in the American and Canadian groundwater sources sampled.

Treated water sources
(PMRA1852616, 1852618, 1852619, 1774484, 1852614, 2312776, 2312778, 2505827, 2505828 and 2589776)

A total of 1,807 samples of treated water were analyzed for cyhalothrin residues in the United States only. There were no data for Canada. There were no detections of cyhalothrin residues in treated water sources sampled.

Surface water sources relevant for both human health and aquatic risk assessments
(PMRA 1403269, 1971119, 2544468, 2561884, 1852616, 1852618, 1852619, 1774484, 1852614, 2312776, 2312778, 2505827, 2505828, 2589776 and 2589777)

A total of 18,745 ambient surface water samples were analyzed for cyhalothrin residues in Canada and the US. Cyhalothrin was detected in 100 ambient surface water samples analyzed (0.5%). The maximum concentration of cyhalothrin residues detected was 0.185 µg a.i./L from Monterey Quail Creek in California. Considering Canadian data only, cyhalothrin was detected in ambient surface water in 3 out of the 1,165 water samples analyzed (0.3%). In Canada, the highest concentration of cyhalothrin in surface water was 0.17 µg/L detected in Quebec.

Other surface water sources relevant for aquatic risk assessments
(PMRA 2035772, 2482494, 2526150, 2548876, 2548877, 2387015 and 2526131)

A total of 447 water samples from sources unlikely to serve as a drinking water source, but relevant for aquatic risk assessment purposes, were analyzed in Canada and the US. Cyhalothrin was detected in 71 samples (16%). All of the detections occurred in the US. The maximum concentration detected was 79.7 µg a.i./L in a water sample from a playa wetland surrounded by cotton fields on the Southern High Plains of the United States (which includes states such as Texas, New Mexico and Oklahoma). The second highest concentration detected was 27.2 µg a.i./L from playa wetlands surrounded by grassland in the same geographic area of the US. Apart from detections on the southern High Plains, the next highest detection was 0.125 µg a.i./L in California. There were no detections of cyhalothrin in the 118 samples analyzed in Canada.

Discussion and Conclusion

Potential drinking water sources

Based on available monitoring data, cyhalothrin is seldom detected in water across Canada and the US. The maximum concentration of cyhalothrin detected in potential drinking water sources was 0.185 µg a.i./L, based on a sample from California. The levels observed in the United States may not be representative of Canadian exposure levels because rates of use for lambda-cyhalothrin are higher in the United States than in Canada.

Surface water monitoring data may miss peak concentrations, as sampling is typically sporadic and peak concentrations can be flushed through a system in a short amount of time after a runoff event. Therefore, for surface water, EECs generated through modelling are typically better suited for use in an acute dietary risk assessment than surface water monitoring values.

Groundwater monitoring is less likely to miss peak concentrations than surface water monitoring, as groundwater moves slowly and concentrations are less affected by rainfall events. Both monitoring data and groundwater modelling indicate that cyhalothrin is not expected in groundwater.

Surface water relevant for aquatic risk assessments

For aquatic risk assessment purposes, the highest concentration of cyhalothrin detected in water was 79.7 µg/L from a playa wetland in the US, which was higher than the peak concentrations predicted by modelling for water bodies 80 cm and 15 cm deep in Canada (Table 20). The highest detection was associated with use on cotton, which is not grown in Canada. The second highest detection, 27.2 µg a.i./L, was associated with grasslands in the Southern High Plains of US. In another data set from California, the highest detection of cyhalothrin was 0.125 µg a.i./L. Because the rates of cyhalothrin application are higher in the United States than in Canada, these detections may not be a good representation of environmental concentrations in Canada. Based on Canadian monitoring data, lambda-cyhalothrin seldom detected in water (0.3% or less of samples). The maximum concentration reported was 0.17 ug/L in Quebec. Based on the low frequency of lambda-cyhalothrin detection in Canadian surface waters, its low solubility in water, and environmental fate studies that demonstrate that lambda-cyhalothrin readily partitions into sediment, the potential for acute exposure of aquatic organisms to lambda-cyhalothrin in surface water is expected to be limited. As well, because of the low detection frequency of lambda-cyhalothrin in water, it is difficult to estimate a long term exposure concentration based on available water monitoring data; as such, a chronic aquatic exposure assessment based on monitoring data cannot be conducted.

Appendix XIV Label Amendments for End-Use Products Containing Lambda-cyhalothrin

The label amendments presented below do not include all label requirements for individual end use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the following label statements.

Label amendments for lambda-cyhalothrin technical grade active ingredient labels

The following statements must be added to the section entitled ENVIRONMENTAL PRECAUTIONS:

TOXIC to aquatic organisms.

DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.

The following statements must be added to the section entitled DISPOSAL:

"Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal or provincial regulations. For additional details and clean up of spills, contact the manufacturer or the provincial regulatory agency."

Label Amendments for Commercial Class Products Containing Lambda-Cyhalothrin

DIRECTIONS FOR USE

Uses

The following uses must be removed from all commercial class end-use product labels:

- All food and feed uses.
- Turf applications in residential areas (except for golf courses).
- All indoor structural applications in residential areas.

Turf applications in non-residential areas, golf courses and sod farms are permitted. Indoor structural crack and crevice application in non-residential areas is permitted.

Based on indoor crack and crevice application, recommendations to reduce exposure will include application requirements. The registrants are required to include use directions for this application equipment on commercial class labels.

Crack and crevice is defined as an application of pesticides with the use of a pin stream nozzle, into cracks and crevices in which pests hide or through which they may enter a building. It does not permit the treatment of surfaces. Such openings commonly occur at expansion joints, and between equipment and floors. Application is with a low pressure sprayer equipped with a pin stream spray nozzle for indoor crack and crevice treatment.

Residential areas are defined as any use site where the general public, including children, could be exposed during or after application. For structural uses, in residential sites, this includes homes, schools, restaurants, public buildings or any other areas where the general public including children may potentially be exposed. Non-residential areas include, but are not limited to: industrial/commercial indoor sites (for example, laboratories, warehouses, food granaries); modes of transport in areas where passengers are not present (for example, buses, railcars, trailers); and animal housing (for example, livestock housing and poultry, pet kennels).

Statements must be added to include the following directions:

For all formulations:

> "This product must not be applied as band, spot or bedbug treatment."

For all product labels that have chokecherry shelterbelt listed:

> "Do not harvest treated chokecherries for food."

Restriced Entry Interval

Statements must be added to include the following directions:

For sod farms, tobacco, and shelterbelts:

> "Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours."

For gardens and trees in residential areas:

> "Re-entry is permitted once residues have dried."

For outdoor ornamentals:

> "Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 3 days for all activities with foliar contact with cut flowers. For all other outdoor ornamentals, the REI is 12 hours for all activities."

Remove the following statement from all labels:

For outdoor ornamentals:

> "Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 6 days for the postapplication activity of cutting flowers."

PRECAUTIONS

General Label Improvements

The following statement must be added to all product labels:

> "Apply only when the potential for drift to areas of human habitation or areas of human activity (excluding golf courses) such as houses, cottages, schools and recreation areas including parks, school grounds, and playing fields is minimal, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings."

Personal Protective Equipment

Label statements must be amended (or added) to include the following directions to the appropriate labels:

A. Custom groundboom application of liquids

"If handling 10 kg or more of the active ingredient in a day, use a closed cab that provides both a physical barrier and respiratory protection. The closed cab must have a chemical-resistant barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab. Respirators and chemical-resistant gloves are not required to be worn inside the closed cab, but have them ready for leaving the cab during calibration, repair or cleaning of equipment."

B. Handheld application of liquids

"For mechanically-pressured handguns: Also wear a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides, or a NIOSH approved canister approved for pesticides. Do not handle more than 0.35 kg of the active ingredient per person in a day. These restrictions are in place to minimize exposure to individual applicators. Application may need to be performed over multiple days or using multiple applicators."

TOXICOLOGICAL INFORMATION

The following must be added on the labels of all products under the section entitled TOXICOLOGICAL INFORMATION:

> "Skin exposure may cause transient sensations (tingling, burning, itching, numbness)."

ENVIRONMENTAL PRECAUTIONS

The following statements must be added on the labels of all products under the section entitled ENVIRONMENTAL PRECAUTIONS:

TOXIC to aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE.

TOXIC to small wild mammals.

TOXIC to bees. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site. Avoid application during the crop blooming period. If applications must be made during the crop blooming period, restrict applications to the evening when most bees are not foraging. Avoid applications when bees are foraging in the treatment area in ground cover containing blooming weeds. To further minimize exposure to pollinators, refer to the complete guidance "Protecting Pollinators during Pesticide Spraying – Best Management Practices" on the Health Canada website (www.healthcanada.gc.ca/pollinators)."

TOXIC to certain beneficial insects. Minimize spray drift to reduce harmful effects on beneficial insects in habitats next to the application site such as hedgerows and woodland."

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

For product formulations that contain aromatic petroleum distillates, the following statement is required:

This product contains (an) active ingredient(s) and aromatic petroleum distillates which are toxic to aquatic organisms.

The following statements are required under the section entitled DIRECTIONS FOR USE:

As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

To protect pollinators, follow the instructions regarding bees in the Environmental Precautions section.

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) medium classification. Boom height must be 60 cm or less above the crop or ground.

Airblast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) medium classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length **MUST NOT** exceed 65% of the wing- or rotorspan.

Buffer zones:

Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop	Buffer Zones (metres) Required for the Protection of:			
		Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:	
		Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
Field sprayer	Barley, buckwheat, pearl millet, proso millet, oats, rice, rye sorghum, teosinte, triticale, wheat, wild rice, potatoes, tomatoes, carrots, celery, flax, leaf lettuce, mustard, canola, summer-fallow, unimproved pasture, poplar and willow, sunflowers, sweet potato, timothy (grown for hay or seed), asparagus	55	25	120	120
	Alfalfa	65	30	120	120
	Broccoli, chinese broccoli (gai lon), brussels sprouts, cabbage, chinese cabbage (napa), chinese cabbage mustard (gai choy), cauliflower, cavolo broccolo and kohlrabi), garlic, onion	110	50	120	120
	Corn (including field, pop and sweet types, and crops grown for seed production)	120	55	120	120
	Lentils, Beans, succulent and dry edible*, chickpeas, favabeans, peas (includes dwarf pea, edible-pod pea, snow pea, sugar snap pea, english pea, garden pea, green pea), pigeon pea, soybeans, Chayote (fruit), chinese waxgourd, citron melon, cucumber, gherkin, edible gourd, momordica spp., muskmelon, pumpkin, summer squash, winter squash, watermelon	120	60	120	120
	Turf (sod, golf course, home, industrial and commercial lawns)	120	90	120	120

Airblast	Chokecherry, shelterbelts	Early growth stage	50	45	70	60
		Late growth stage	40	35	60	50
	Pears, tobacco (soil treatment)	Early growth stage	55	45	75	65
		Late growth stage	45	35	65	55
	Saskatoon berries	Early growth stage	65	55	80	75
		Late growth stage	55	45	70	60
	Apples, cherries, nectarines, peaches, plums, strawberries,	Early growth stage	65	60	85	75
		Late growth stage	55	50	75	65
Aerial	**PCP 24984:** Alfalfa, unimproved pasture, flax, sunflowers, canola, mustard, grass mixtures, summer-fallow	Fixed wing	550	150	800	800
		Rotary wing	450	150	800	800
	PCP 29052: Alfalfa, unimproved pasture, flax, sunflowers	Fixed wing	550	175	800	800
		Rotary wing	450	150	800	800
	PCP 24984: Buckwheat, pearl millet, proso millet, rice, rye sorghum, teosinte, triticale, wild rice, chickpeas, dry edible beans, fava beans, soybeans,	Fixed wing	800	425	800	800

	lentils, potatoes, barley, wheat, oats, succulent beans, succulent peas, field peas, dry peas and soybeans	Rotary wing	600	375	800	800
	PCP 29052: Lentils, potatoes, barley, wheat, oats, succulent beans, succulent peas, field peas, dry peas, chickpeas, dry edible beans, fava beans, soybeans	Fixed wing	800	450	800	800
		Rotary wing	700	400	800	800
	PCP 29052: Canola, mustard	Fixed wing	800	575	800	800
		Rotary wing	800	450	800	800
	PCP 29052: Dwarf pea, edible-pod pea, snow pea, sugar snap pea, English pea, garden pea, green pea, pigeon pea **PCP 30404:** Chickpeas, dry edible beans, fava beans, soybeans, Phaseolus spp., Lupinus spp., Vigna spp., dry lablab beans **PCP 29052, PCP 24984, PCP 30325:** Corn (including field, pop and sweet types, and crops grown for seed production) **PCP 24984:**	Fixed wing	800	800	800	800

	Poplar (Populus spp.) and willow (Salix spp.) plantings, including short-rotation-intensive-culture (sric), their hybrids and their planting stock	Rotary wing	800	800	800	800

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency web site. **Buffer zones of 120 m (field sprayer) or 800 m (aerial sprayer) CANNOT be modified.**

The following statements must be added under the section entitled STORAGE:

To prevent contamination store this product away from food or feed.

The following statements must be added under the section entitled DISPOSAL section where the container is recyclable:

DO NOT reuse this container for any purpose. This is a recyclable container, and is to be disposed of at a container collection site. Contact your local distributor/dealer or municipality for the location of the nearest collection site. Before taking the container to the collection site:

1. Triple- or pressure-rinse the empty container. Add the rinsings to the spray mixture in the tank.

2. Make the empty, rinsed container unsuitable for further use.

If there is no container collection site in your area, dispose of the container in accordance with provincial requirements.

For product labels with greenhouse uses:

In addition to applicable statements above, the following statements must be added under the section entitled ENVIRONMENTAL PRECAUTIONS:

DO NOT allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters.

TOXIC to bees and other beneficial insects. May harm bees and other beneficial insects, including those used in greenhouse production. DO NOT apply when bees or other beneficial insects are actively visiting the treatment area.

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A. Studies Considered in the Chemistry Assessment

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2448130	USEPA. Undated. Data Evaluation Report. Cyhalothrin Oral Toxicity Study in Beagle Dogs (Repeated Daily Dosing for 26 Weeks). Toxicology Branch, Health Effects Division. Undated. DACO 12.5.4
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C. Information Considered in the Dietary Assessment

List of Studies/Information Submitted by Registrant

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788990, 1163844	1992. Lambda-Cyhalothrin (ICIA0321): Residue Levels of the Major Metabolites in Dairy Cows Fed on a Diet Containing the Insecticide; Report Series RR 92-028B.
788992	1986. PP321: Residue Transfer Study with Laying Hens fed on a Diet containing the Insecticide; Report Series RJ 0473B.
789002	2000. Analytical Method for the Determination of Lambda-Cyhalothrin and R157836 in/on Canola Seed, Meal and Oil Samples; CCRL-MTH-022 Revision No. 1.
789003	2000. Analytical Method for the Determination of Lambda-Cyhalothrin and R157836 in/on Pasture Grasses/Forage; CCRL-MTH-023 Revision No. 1.
789006, 1235028	1993. Lambda-Cyhalothrin (ICIA0321): Stability of Residues of Lambda-Cyhalothrin and its Epimer
789012	2000. Lambda-Cyhalothrin: Residue Levels on Pastures from Trials Conducted in Canada during 1999; Report Number RR00-039B.
789016, 1269514	2000. Lambda-Cyhalothrin: Residue Levels on Processed Commodities of Canola from a Trial Conducted in the United States during 1999. Zeneca Ag Products, Zeneca Inc. Report No. RR 00-037B.
789020	2002. Lambda-Cyhalothrin Residue Levels on Canola (seed) from Trials Conducted with Matador 120EC and Warrior Insecticides in Canada During 2001; Project No. CER07102/01.
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789022, 1269509	1999. Lambda-Cyhalothrin: Residue Levels on Canola from Trials Conducted in Canada during 1998; Report Number RR99-059B.
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789026	2002. Lambda-Cyhalothrin: Residue Levels on Pastures (Green Forage) from Trials Conducted with 120 CS and 120 EC Formulations in Canada during 2001. Report No. CER07101/01.
822914	1997. Lambdacyhalothrin in Bovine Tissues; INSECT-014-Lambdacyhalothrin.
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920538, 920576, 1082945	2002. Lambda-Cyhalothrin – Residue Levels on Dry Field Peas (Seed) from Trials Conducted with 120 CS and 120 EC Formulations in Canada during 2001; Project No. CER07104/01.
920540, 920578, 1082938	1997. Lambda-Cyhalothrin (ICIA0321): Residue Levels on Dried, Shelled Peas and Beans from Trials Conducted in the United States during 1996; Report Series RR 97-016B.
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1090038	1989. Residues of lambdacyhalothrin and its major metabolites in cattle tissue following repeated application of a 1% pour on; Report CIBH 88-3.
1133385	2005. Lambda-cyhalothrin: Magnitude of the Residue on Green Onion; Study # AAFC03-009.

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1160327	1990. ICIA0321 and Metabolites: Magnitude-of-the-Residue Study on Tomatoes; Report Number RR 90-414B.
1160328	1991. ICIA0321 and Metabolites: Magnitude-of-the-Residue Study on Sweet Corn, Forage, Ears and Cannery Waste; Report Number RR 90-430B.
1160330	1992. Lambda-Cyhalothrin (ICIA0321): Magnitude of the Residue Study on Dry bulb onions; Report Number RR 91-062B.
1160331, 1505846, 2330717	1991. Lambda-Cyhalothrin (ICIA0321) - Magnitude of the Residue Study on Peanuts; Report Number RR 90-420B.
1160333	1994. Lambda-cyhalothrin (ICIA0321): Magnitude of the Residue Study on Sunflowers
1160336	1987. Karate: PP321 Residues on Sweet Corn Kernals and Cobs; Report Series TMU3128/B.
1160338	1987. Distribution of PP321 and R157836 Residues in Sunflower Processing Fractions; Report Series TMU3113/B.
1160339	1990. ICIA0321 (Lambda-cyhalothrin) – Magnitude of the Residue Study on Broccoli; Report Number RR 90-427B.
1160341	1991. Lambda-cyhalothrin (ICIA0321) Magnitude of the Residue Study on Wheat; Report Number RR 91-011B.
1160352	1991. ICIA0321: Magnitude of the Residue Study on Field Corn and Popcorn; Report Number RR 90-428B.
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1163845, 2235673	1985. PP321: Metabolism in Laying Hens; Report Series RJ O453B.
1163846	1982. Cypermethrin: Residues in Eggs and Tissues of Domestic Fowl Following Repeated Oral Dosing with [14C-phenoxy]cypermethrin; Report SBER.82.002.
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1163852	1986. PP321: Quantification and Characterisation of Radioactive Residues found in Soya Leaves from Plants Treated with 14C-PP321; Report Series RJ O507B.
1163853	1990. Lambda-Cyhalothrin: Quantification and Characterisation of Radioactive Residues in Grain from Wheat Treated with 14C-Lambda-cyhalothrin; Report Series RJ O836B.

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1163856	1987. PP321: Residue levels on Strawberries from trials carried out in Canada during 1986; Report Series M4401B.
1163857	1987. PP321: Residue levels in Brussel Sprouts from a trial carried out in the Netherlands during 1986; Report Series M4481B.
1163915, 1954444	1988. PP321: Storage Stability in Frozen Crop Samples; Report Series M4845B.
1163927	1993. Part III: Final Report on Storage Stability of Pyrethroid Metabolites (PP890, 3-PB Acid, 3-PB Alcohol and DCVA) in Raw Agricultural Commodities
1163936	1987. PP321: Rotational Crop Study Using 14C-Radiolabelled PP321; Report Series RJ 0593B.
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1167301	1989. Residue Levels of ICIA0321 in Peaches; Report Number CRR109.
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1183034	1987. PP321: Residue level in Maize (sweet Corn) from a trial carried out in Canada during 1986.
1183037	1990. ICIA0321 (Lambda-cyhalothrin) – Magnitude of the Residue Study in Processed Tomato Products; Report Series RR 90-419B.
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1190911	1989. Residues of lambdacyhalothrin and its major metabolites in cattle tissue following repeated application of a 1% pour-on; Report Number CIBH 88-3.
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1203385	1985. PP321: Residue levels in Stone Fruits from 1984 trials in Canada; Report Series M4004B.
1203392	1986. PP321: Residue levels on Brussel Sprouts from a 1985 trial in Canada; Report Series M4199B.

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1215666	1987. PP321: Residue levels in Canola from a trial carried out in Canada during 1986; Report Series M4381B.
1215666	1985. PP321: Residue levels in Sunflower Seed from 1984 trials in Canada; Report Series M4047B.
1215666	1987. PP321: Residue levels in Flax from a trial carried out in Canada during 1986; Report Series M4408B.
1215666	1987. PP321: Residue levels in Wheat from a 1984 trial in Canada; Report Series M4015B.
1215670	1987. PP321: Residue levels in Wheat from trials carried out in Canada during 1986; Report Series M4455B.
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1218823	1988. Residue Levels of PP321 in Barley Grain and Straw; Report Number CRR102.
1218834	1988. Residue Levels of PP321 in Wheat Grain and Straw; Report Number CRR101.
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1248969	1984. Cyhalothrin (ICI 146,814): The Disposition and Metabolism [14C]-ICI 146,814 in the Dog; Study Number 146814 KMD 005.
1248971	1985. PP321: Metabolism in a Goat; Report Series RJ O435B.
1248997	1983. Cyhalothrin: Metabolism in Cabbage; Report Series RJ O308B.
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1249646	1985. PP321: Residue levels in Potatoes from 1984 trials in Canada; Report Series M4033B.
1326185	2004. Lambda-Cyhalothrin – Residues Levels on Edible-Podded Beans (runner bean, snap bean or wax bean) from Trials Conducted with Matador or Warrior in Canada During 2003; Project No. CER07124/03.
1326186	2004. Lambda-Cyhalothrin – Residues Levels on Edible-Podded Peas (dwarf-pea, edible-pod pea, snow pea, sugar snap pea) from Trials Conducted with Matador or Warrior in Canada During 2003; Project No. CER07125/03.
1326188	2002) Lambda-Cyhalothrin – Residue Levels on Soybeans (Seed) from Trials Conducted with Matador Insecticide and Warrior Insecticide in Canada during 2002; Project No. CER 07117/02.

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1505747	1999. Lambda-Cyhalothrin: Residue Levels in Olives Trials Carried out in Spain during 1998; Report Series 17870.
1505752	2001. Lambda-cyhalothrin Residue Levels in Olives and Processed Fractions from Trials carried out in Spain during 1999/2000; Report Series AF/4733/ZE.
1505754	2004. Residue Study with Lambda-cyhalothrin (PP321) in or on Olives and processed fractions in Greece; Report Series AF/7564/SY.
1505756	2004. Residue Study with Lambda-cyhalothrin (PP321) in or on Olives and processed fractions in Greece; Report Series AF/7565/SY.
1505758	2005. Lambda-Cyhalothrin: Residue Study on Olives in Italy and Spain, Southern Europe; Report Number AF/7928/SY.
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